



Government Corona Commission

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# PRIORITY VACCINATION OF PERSONS AT INCREASED RISK DURING THE 2021 COVID-19 PANDEMIC IN BELGIUM

Report of the Working Group on Vaccination Strategy Organisation (Vaccination Task Force)

18 March 2022





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# 1. INTRODUCTION

## 1.1. SITUATION AND BASIC PRINCIPLES

In this first part of this report, we describe how the priority vaccination of persons at higher risk was organised during the COVID-19 pandemic in Belgium. In the second part of this report, we attempt to answer the question: What difference did the priority vaccination approach have on hospitalisation, admission to Intensive Care and mortality?

The COVID-19 vaccination campaign was based on a number of key principles, internationally known as the *Quintuple Aim*:

- achieving a positive quality experience for the citizen;
- an improvement in health at the population level;
- more social justice in the provision of assistance (leave no one behind);
- attention for the welfare of caregivers;
- and creating as much "value" as possible with the resources deployed.

In September 2020, the US National Academy of Medicine published a report entitled<sup>a</sup> *Framework for equitable allocation of COVID-19 vaccine*, in which these principles were translated into three major criteria for the procedures followed: they had to be appropriate, transparent and scientifically sound.

That is why the starting point is always the scientific evidence – to the extent any is readily available in the midst of a new pandemic (a mandate from the Superior Health Council). Then the Task Force turned the evidence into a vaccination strategy. This was then politically approved in the Interministerial Conference, by the Ministers of Health. The priorities used show the focus on social justice. Vaccination strategy is fundamentally based on *equity* (social justice): access to vaccination was granted first to those at highest risk of infection and those at heightened risk of serious complications (hospitalisation, ICU admission, death).

A clear choice was made for a participatory model. All stakeholders were able to contribute, through consultation, to the choices for priority vaccination and an accessible, effective and transparent vaccination process. To ensure these principles, the Inter-federal Government Corona Commission was expanded in November 2020 to include a COVID-19 vaccination strategy task force. Within the Task Force, an Organisation Working Group was established, which initially focused on the vaccination of 45-65-year-olds with co-morbidity. Later, this remit was expanded to supporting the implementation of the entire vaccination strategy.

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<sup>a</sup> National Academies of Sciences, Engineering, and Medicine. 2020 Framework for equitable allocation of COVID-19 vaccine. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25917>

## 1.2. GOVERNANCE VACCINATION STRATEGY ORGANISATION

### 1.2.1. INTER-FEDERAL GOVERNMENT CORONA COMMISSION: 'THE OIL THAT MAKES THE MACHINE RUN'

The large-scale vaccination of the entire population in the midst of a pandemic was a first for our country. Therefore, it was important to bring all those involved on board from the outset, including to ensure a smooth flow of information and communication. For this reason, the Inter-federal Government Corona Commission was established as '*the oil that makes the machine run*' (Pedro Facon, Corona Commissioner, October 2020).

The coalition agreement of September 2020 stated: 'The government will appoint a competent commissioner, assisted by a team, for a **period of twelve months to ensure coordination of the health policy of the federal government and that of the federated states**. The mandate is renewable for six-month periods. The commissioner is also assisted by an inter and multi-disciplinary scientific committee, which may be supplemented by foreign scientists, and by a team of project managers, who keep track of **new evidence about the virus in a structured way and also monitor the societal, economic and social impact of measures**.

### 1.2.2. TASK FORCE ON OPERATIONALISATION OF THE COVID-19 VACCINATION STRATEGY

In order to steer the roll-out of the vaccination programme in the right direction, an Inter-federal Task Force on Operationalisation of the COVID-19 Vaccination Strategy, known as the Vaccination Task Force (TF), was set up within the Government Corona Commission. That Task Force was responsible for developing the vaccination strategy. It also had to determine, assign and support all necessary actions. Its job was to coordinate. This Task Force consisted of representatives of federal and regional government departments, scientists and, where necessary, representatives of professional organisations and working groups. A core team of about 10 people took care of its daily operations.

The four federated states were responsible for the practical organisation of the vaccination. This was done in close consultation with the Task Force, on which they were also represented.

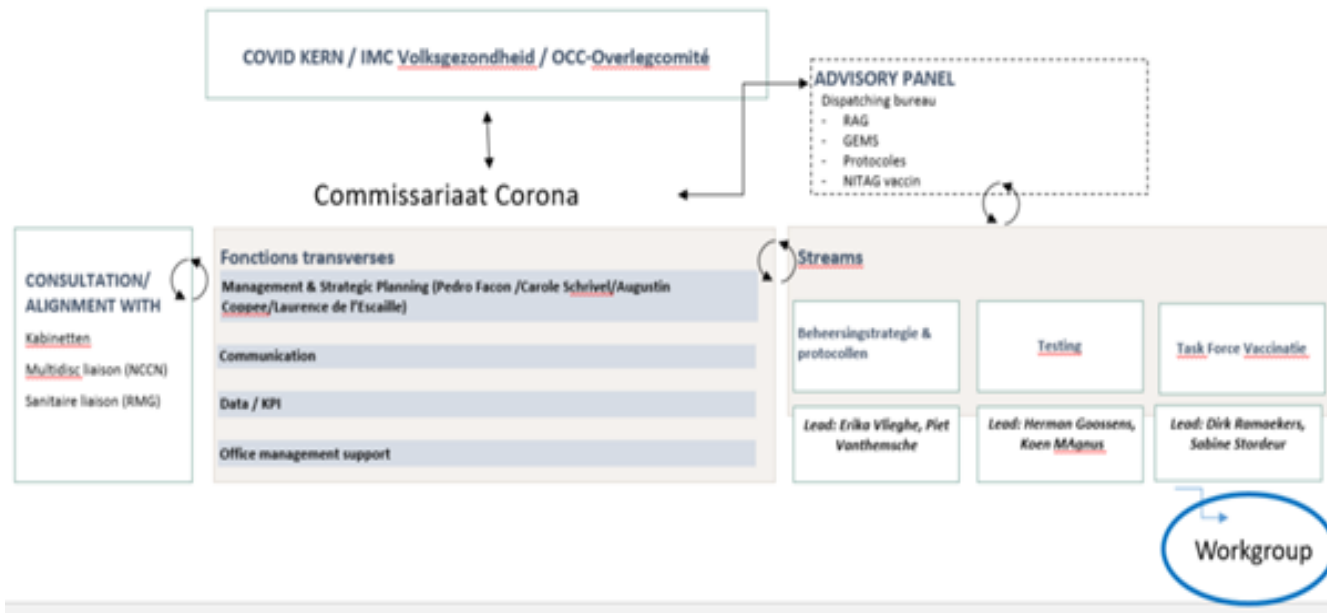
Based on the opinion of the Vaccination Task Force of 5 December on the COVID-19 vaccination strategy for Belgium ([https://d34j62pglfm3rr.cloudfront.net/downloads/Note\\_TF\\_Strategy\\_Vaccination\\_NL\\_0312\\_post\\_press.pdf](https://d34j62pglfm3rr.cloudfront.net/downloads/Note_TF_Strategy_Vaccination_NL_0312_post_press.pdf)), the Inter-ministerial Conference on Public Health decided to prioritise vaccinating people with certain co-morbidities (hereafter referred to as "high-risk patients") against COVID-19.

### 1.2.3. WORKING GROUP ON VACCINATION STRATEGY ORGANISATION

In order to prepare for the vaccination of patients aged between 45 and 65 with co-morbidities, a working group on *vaccination of high-risk individuals aged 45-64* was established within the federal Task Force on Vaccination in November 2020. Its first task was to develop a system to identify persons at heightened risk of serious complications (hospitalisation, ICU admission, death) and to invite them for vaccination as a priority. Afterwards, its tasks were extended and the working group was renamed *organisation vax strategy* (Vaccination Strategy Organisation – hereafter 'the Working Group').

Internal and external communication received particular attention.

Figure 1



The key stakeholders for the vaccination of the high-risk patients were represented on this working group:

- professional associations of general practitioners and medical specialists
- professional associations of pharmacists
- the insurance institutions/health insurance funds/IMA
- patient associations
- the Vaccination Task Force
- a medical law specialist
- university experts
- the federal government (e.g. ICT, data management, privacy legislation) and the federated states, which were responsible for the operational roll-out of vaccinations



A member of the Vaccination Task Force chaired the Working Group. They met weekly, or whenever necessary, which ensured ongoing coordination. The participants in the Working Group, in turn, ensured that the necessary information flowed through to the relevant members and staff, including newsletters, mailings, websites and webinars. On the other hand, the chairman reported regularly to the Vaccination Task Force. In this way, everyone was kept on the same page.

### **1.3. BELGIAN HEALTHCARE SYSTEM: DIVISION OF COMPETENCES ORGANISATION OF COMPULSORY HEALTH INSURANCE, THE ROLE OF THE CANCER REGISTRY FOUNDATION**

#### **1.3.1. THE BELGIAN HEALTHCARE SYSTEM**

In Belgium, the healthcare system is broadly similar to most other European countries, but is unique from an insurance perspective<sup>b</sup>.

First are the primary healthcare providers with general practitioners playing a central role. The majority of general practitioners are self-employed in independent solo or group practices, possibly together with other primary healthcare providers such as nurses, physiotherapists, dieticians, etc. Solo practices are decreasing in number. Their financing is purely performance-related, with a few exceptions such as waiting fees, reimbursement for the Global Medical Record (GMD). Furthermore, there are increasing numbers of district health centres: medical centres that are financed by a flat annual fee per registered patient. Nurses and physiotherapists are part of the permanent team at these centres. A patient cannot use both systems simultaneously. In a few years' time, the number of independent GP group practices and the number of district health centres will be about the same. Independent general practitioners' group practices are increasingly using the Global Medical Record as a registration tool. Increasingly, patients are only charged the personal contribution; the insured amount is settled directly with the mutual health insurance company.

Next come the 103 general hospitals which have recently established 25 hospital networks. The 7 university hospitals and the 17 hospitals linked to universities offer tertiary care. Hospital care is increasingly evolving towards primary and more multidisciplinary care due to the increase in chronic diseases and demographic ageing. There is limited institution-based funding for these hospitals in addition to patient-based funding for performance. In Belgium, we have an extremely precise nomenclature. It is an inventory of all possible medical treatments as well as of the compensation that may be charged under the compulsory health insurance. With regard to hospitals, a first attempt at pathology financing is currently being introduced, called low-variable care, which is also person-following.

In Belgium, there is no gatekeeper: patients have the freedom to consult any level of care on their own initiative and to be reimbursed for this if they have health insurance (= almost everyone see point 1.3.3.). Moreover, waiting lists are almost non-existent. Waiting lists have arisen recently mainly in disciplines where there is a shortage of doctors, but this is also due to a lack of a proper division of tasks (e.g. between GPs and specialists). Since 1997, the number of medical students has been limited by an entrance exam.

On 1 May 2002, the GMD was launched in the interest of patients, to better coordinate their care, prevent 'medical shopping', increase the quality of care and avoid unnecessary expenditure on social health insurance. One GP (or GP group) has an electronic file that, in theory, contains all of a patient's medical information. Each doctor who attends to a patient in consultation reports to the GMD general practitioner. Patients followed in a district health centre or flat-rate practice automatically have a GMD

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<sup>b</sup> [The performance of the Belgian healthcare system – Report 2019 – KCE \(fgov.be\)](#)

record. Financial incentives have been introduced to support this non-binding system with an annual flat fee for the GP (32 euros in 2021) and a discount for the patient on the GMD GP's fee. However, there are large regional differences in the use of the GMD. Flanders is home to 58% of the population. A proportional proportion of GMD general practitioners live in Flanders (58.5%). More than half (61.5%) of these GPs have more than 500 patients with a GMD. Wallonia is home to 32.5% of GMD general practitioners which is proportional to the region's population (31%), but only 46% of GMD general practitioners have more than 500 patients with a GMD. In Brussels, there are fewer GMD general practitioners (9%) compared to the population (11%) and the majority (65.5%) have fewer than 500 patients with a GMD. In Flanders, GP practices are larger and GMD use is noticeably higher. As a result of COVID, additional funding of €20 per GMD file was granted to compensate for all the 'fire-fighting' work done by GPs and their contribution to selecting high-risk patients.

**Table 1: 2019 CM data**

Region	% inhabitant s Belgium	% patients with a GMD	% GMD general practitioner s	% GMD general practitioners with x number of patients		
				< 100 patients	100<x< 500 patients	>500 patients
Flanders	58	82	58.5	9	13.5	36
Wallonia	31	69	32.5	7.5	10	15
Brussels	11	59	9	2.9	3	2.8

### 1.3.2. THE DISTRIBUTION OF COMPETENCES IN THE BELGIAN HEALTHCARE SYSTEM

Following six constitutional reforms, the federal level has partially transferred its competences for the healthcare system to the four communities: Flanders, Wallonia, Brussels and the German-speaking Community. Regional competences include welfare, care for the elderly, prevention, hospital recognition and infrastructure and organisation of primary care. This has created regional differences in the organisation of care. In Flanders, there are 60 primary healthcare zones (ELZ) with their respective levels of care. A Health Council is composed of a maximum of 24 people including local authorities, primary healthcare providers, welfare representatives (e.g. social work services of the mutual health insurance companies, home care services, etc.), user associations and experts as needed. They have played an important role in the vaccination campaign. Wallonia and Brussels lack these smaller regional structures.

Vaccination is essentially preventive and therefore a competence of the federated entities (communities and regions). They are responsible for the vaccination strategy, including the adjustment and implementation of the vaccination calendar at community level, the public procurement of the vaccines that they pay for, the promotion of vaccination (through awareness campaigns), the evaluation of vaccination costs, vaccination coverage studies, and so on. Consequently, there are also slight differences

between the communities' vaccination programmes. For the Flemish Community (in Flanders and Brussels), the Agency for Care and Health (AZG) is the central body responsible for vaccination policy, based on the advice of the Flemish Vaccination Organisation.

In the French-speaking Community (Fédération Wallonie-Bruxelles, FWB), responsibilities are divided between different agencies depending on the population's location or age group: the Office national de la Naissance et de l'Enfance (ONE) [National Office for Birth and Childhood] for young children, schools and for whooping cough vaccination of pregnant women in FWB, and the Agence pour une Vie de Qualité (AViQ) [Agency for a High-Quality Life] for adults in Wallonia.

The Joint Community Commission (COCOM) is responsible for vaccination policy in bicomunity institutions and for the measures imposed on individuals living in the bilingual Brussels-Capital Region.

The German-speaking Community (Deutschsprachige Gemeinschaft) is responsible for its own vaccination programme but uses the platform of the French-speaking Community (e.g. for public tenders).

The Belgian federal authorities, including the Federal Public Service (FPS) Health, Food Chain Safety and Environment, are responsible for specific aspects of vaccination policy. This is, for example, the case for polio, where the federal government is in charge of controlling vaccination against poliomyelitis, as the compulsory nature of this vaccination in infants is rooted in a federal competence. A COVID-19 vaccination mandate (e.g. for healthcare personnel as of 2022) is also a personnel matter and therefore federal in nature.

The elderly population was severely affected by COVID-19 early in the pandemic, especially in residential care homes. These facilities required help from hospitals which are under federal jurisdiction. Pharmaceutical specialities are a federal competence, such as purchasing vaccines, quality control, etc., while the organisation of vaccination is a regional competence, so the pharmacists preparing the vaccines in the vaccination centres were financed by the regions.

Because of this interweaving of powers, it was soon clear that ongoing consultation between the federal and regional entities was a necessity. Their presence in both the Task Force and the Working Group was essential.

### 1.3.3. THE ORGANISATION OF SOCIAL HEALTH INSURANCE

The way social health insurance is organised in Belgium is unique in Europe. Health insurance, financed by social security, is a federal competence and is organised by the National Office of Sickness and Disability Insurance (RIZIV in Dutch). The RIZIV receives its budget mainly through social contributions on labour from employers, employees and self-employed workers, based on the principle of solidarity. Health insurance is compulsory for all Belgian residents and in principle free, except for persons who have an income other than from employment. Through various correction mechanisms, almost everyone is insured against illness. In 2020, 11,360,839 people were insured<sup>c</sup>.

#### 1.3.3.1. COMPULSORY HEALTH INSURANCE

The health insurance funds implement Belgium's compulsory health insurance. They meet healthcare needs and grant replacement income in case of incapacity for work due to illness. Any payment to a healthcare provider, in a hospital or when purchasing medication in a pharmacy for a person who is eligible for social health insurance

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<sup>c</sup> source RIZIV

benefits is submitted to the health insurance fund. The health insurance funds hold all of these billing data about each of their members. The health insurance funds have a huge amount of data on healthcare use. They are the only bodies who have an overview of their members' healthcare use. For example, an invoice from the purchase of blood-pressure-lowering medication reveals that the person in question suffers from hypertension. Consulting doctors are employed by the health insurance funds and are the only ones who have access to medical diagnoses in certain cases. These doctors are the guarantors of medical confidentiality within the health insurance funds.

But the role of the health insurance funds is broader than mere implementation, and that makes the system unique in Europe. The health insurance funds represent all patients and together they strive for maximum healthcare accessibility and affordability. While they also have financial responsibility to manage budgets prudently. Under the supervision of the RIZIV, the health insurance funds conclude agreements with healthcare providers, including on rates and fees but also on the quality of care and, in certain cases, on quotas.

The system is halfway between a basic health insurance package for everyone (like The National Health Service in England or Caisse primaire in France) and a system of private health insurance companies that negotiate insurance packages for employers (like in the Netherlands). However, the basic package in Belgium is much broader than in the UK or in France. The difference with the Netherlands is that there is no additional premium paid by the insured person and the package of insured care in Belgium is independent of the employer. All health insurance funds collectively negotiate with the RIZIV and thus each health insurance fund offers the same compulsory health insurance package. All health insurance funds provide the same coverage at the same rates for a very broad basic package. The employers are not directly involved, but they have a seat in the General Council of the RIZIV, which has to approve the decisions of the RIZIV (Insurance Committee).

There are five health insurance funds in Belgium, each with a different market share: Landsbond der Christelijke Mutualiteiten (40.4%), Landsbond van de neutrale ziekenfondsen (5%), Nationaal Verbond van de Socialistische Mutualiteiten (28.4%), Landsbond van Liberale Mutualiteiten (5%), Landsbond van de onafhankelijke ziekenfondsen (19.4%). There are also two funds known as 'kassen': the Auxiliary Sickness and Disability Insurance Fund (1%) and the HR Rail Care Fund (0.8%). Individuals are free to choose their fund. Those who do not make a choice are enrolled in the Auxiliary Fund, which is administered by the government. The HR Rail Care Fund is the social insurer for railway personnel and is also an occupational health service. Taken together, the five health insurance funds and the two 'kassen' are known the Insurance Institutions (VI in Dutch).

### 1.3.3.2. SUPPLEMENTARY HEALTH INSURANCE

The health insurance funds provide more than just compulsory health insurance. They are also insurers with their own capital and offer additional services to their members. The health insurance funds were established for and by their members in a spirit of precaution, mutual assistance and solidarity and are governed by the members on the basis of democratic internal elections in the health insurance funds. Originally they were called mutual health insurance companies, but were turned into health insurance funds under the Act of 1990. They are membership associations, a private initiative, not only a service organisation but also a movement and a social profit organisation.

Each health insurance fund offers different supplementary insurance. Often, this insurance is a complementary offer of reimbursement for healthcare not included in the compulsory health insurance, e.g. additional reimbursement for hearing aids. The member contribution for the supplementary insurance differs per health insurance fund (€85.80 to €99/year).

### 1.3.3.3. HEALTH INSURANCE FUND

Health insurance funds are evolving into funds for health. The starting point is the principle of positive health<sup>d</sup>. Central focus is shifting from illness to the person. The emphasis is on the person's resilience, self-management and adaptability and not on his limitations or the illness itself. The individual's state of health is evaluated on the basis of six dimensions: body function, mental well-being, sense of purpose, quality of life, participation and daily functioning. Health promotion was already one of the health insurance funds' core tasks, but the funds are now taking broader initiatives such as tackling disadvantage, *health literacy*, the digital divide, and so on.

For these reasons, the involvement and role of the health insurance funds in the Working Group on Vaccination Strategy was self-evident. After all, all patients are members of a mutual health insurance company who, in turn, are patients' greatest advocates. In the Working Group, they have always fought for the principle of equality and to prioritise vaccination based on the scientific evidence, with particular attention paid to areas where primary care was less developed. They also had a signalling function as complaints are often made to the mutual health insurance companies. During the pandemic they gave advice many people to find the information they needed. When asked, they were also able to explain patients' vaccination status to them and make the necessary appointments.

### 1.3.3.4. THE INTER-MUTUAL AGENCY (IMA)

The health insurance funds have a huge amount of indirect and direct medical data based on their members' billing records. However, these data are scattered across the seven health insurance funds. That is why, in 2002, the health insurance funds jointly founded the IMA in order to be able to analyse this information for all of Belgium. The health insurance funds' data are collated in a pseudo-anonymised way on a single platform. The key that makes it possible to link data to an individual remains in the hands of the health insurance funds. For this purpose, among others, the health insurance funds have united in the National Inter-Mutual College (NIC). In this college, they formulate joint positions on policy (NICpol) and medical matters (NICmed) as well as in terms of procedures (NIC-GZ) in order to defend, as a united front, the rights and needs of the socially insured.

The IMA publishes the IMA Atlas. In addition to demographic and socio-economic data of all inhabitants who are affiliated with Belgium's compulsory health insurance, the IMA databases contain billing data of reimbursed healthcare.

The IMA itself carries out analyses on the data, whether at the request of the legal partners or otherwise. It also carries out research projects in cooperation with or commissioned by federal government agencies, the regions and communities and in cooperation with universities.

### 1.3.4. THE CANCER REGISTRY FOUNDATION

Belgium has a private Cancer Registry Foundation whose role is to collect cancer data (including the registration of all new cancer cases in Belgium), subject it to quality control, process and analyse it, code and store it, report it, make it accessible and protect it. This database is an invaluable source of information and the main starting point for the Foundation's research. It reports to the World Health Organisation (WHO) and the International Agency for Research on Cancer (IARC), among others. The database has been complete for Flanders since 1999 and for all of Belgium since 2004. As a result of the 2006 Health Law, the Cancer Registry Foundation has gained

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<sup>d</sup> positive health: Institute for Positive health – Machteld Huber

additional access to a selection of the health data provided by the health insurance funds. Linking these data with the Cancer Registry's own database has given new impetus to the research projects it carries out both internally and in cooperation with other organisations.

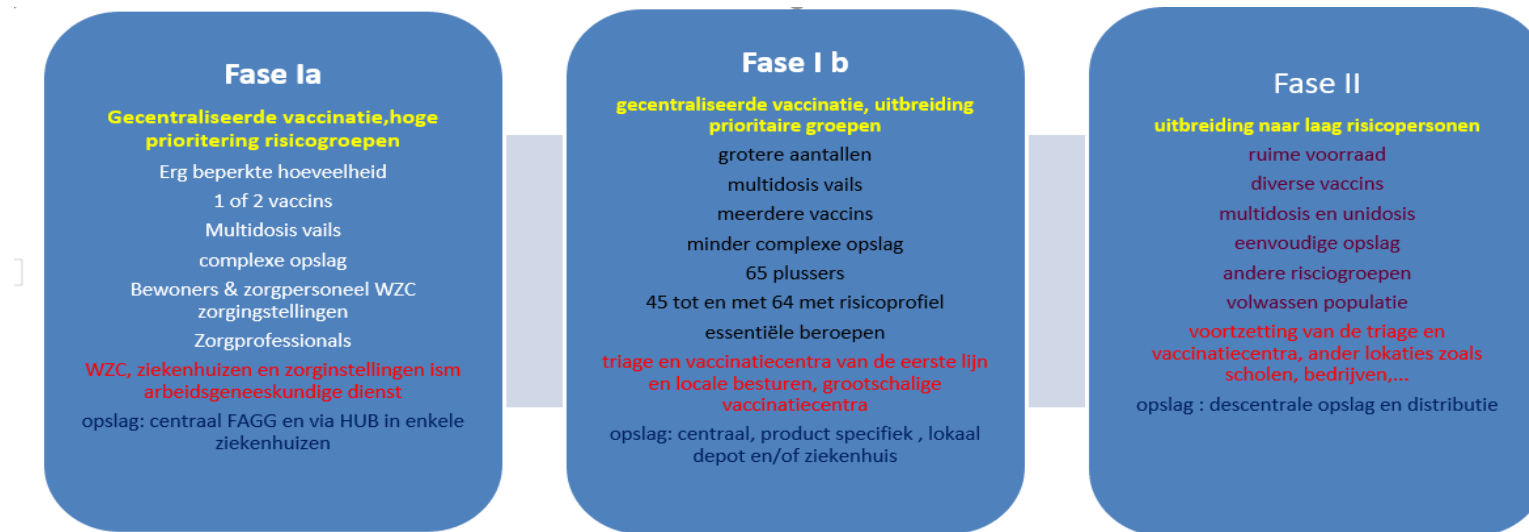
#### 1.4. VACCINATION STRATEGY IN BELGIUM DURING THE COVID-19 PANDEMIC

Belgium made a conscious choice to build priorities into the vaccination schedule, rooted in risks and needs. The aim was to have a positive impact on serious morbidity and mortality, and also to reduce the pressure on the healthcare system (hospitalisations and ICU admissions). This made the vaccination process more complex from an organisational perspective, but it provided an opportunity to explain the philosophy and underlying values (scientific foundation, solidarity and transparency) to the population. This contributed to a more sustainable vaccination process.

- All healthcare workers (including those working in long-term care facilities) to safeguard their health and functional healthcare in the event of another wave of COVID-19 or a pandemic (Phase 1a).
- All persons over the age of 65 (Phase 1a);
- Patients aged 45-65 years with the following co-morbidities and at risk of developing severe COVID-19 pathology (priority 1 - see below):
  - o obesity, diabetes, hypertension, cardiovascular disease, chronic lung, kidney and liver disease and haematological malignancies up to 5 years after diagnosis and all recent solid cancers (or recent cancer treatments) (Phase 1b).
- Followed by vaccination of the rest of the population (Phase 2).

When this opinion was drafted, the estimates for each category of the priority group were very approximate; a total of 4,006,739 people were put forward for priority vaccination.

Figure 2



Phase 1a	Phase 1b	Phase 2
Centralised vaccination, high prioritisation of high-risk groups	Centralised vaccination, expansion of priority groups	Extension to low-risk individuals
Very limited amount	Larger numbers	Large stock
1 or 2 vaccines	Multidose vials	Various vaccines
Multidose vials	Multiple vaccines	Multidoses and unidoses
Complex storage	Less complex storage	Easy storage
Residents & healthcare staff residential care facilities	over 65s	Other high-risk groups
Healthcare professionals	ages 45 to 64 with risk profile	Adult population
	Key occupations	Continuation of triage and vaccination centres, other locations such as schools, businesses...
	Triage and vaccination centres at primary care and local authorities, large-scale vaccination centres	Storage: decentralised storage and distribution

Residential care facilities, hospitals and healthcare institutions in cooperation with occupational health service Storage: centrally FAGG and via HUB in some hospitals	Storage: central, product specific, local depot and/or hospital	
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## 2. SCIENTIFIC JUSTIFICATION FOR THE SELECTION OF THE HIGH-RISK GROUP.

### 2.1. THE SUPERIOR HEALTH COUNCIL

The SHC is a scientific advisory body to the FPS Public Health, Food Chain Safety and Environment. There is a permanent working group on vaccination within the SHC. Its opinions serve as guidance for policy makers and health professionals to protect and improve public health. The Superior Health Council can draw on a network of experts (a pool of some 1,500 experts, as well as 300 appointed experts) and drafts impartial and independent opinions based on a multidisciplinary evaluation of the current scientific knowledge. Vaccination is one of the areas in which it is active. Its decision-making body is the college, which consists of 30 appointed experts and meets monthly. It is responsible for the composition of the working groups that draw up opinions and publications and for the validation of these opinions. Once the opinions have been validated, they are published on the website in the three national languages and in English.

### 2.2. THE OPINION OF THE SUPERIOR HEALTH COUNCIL

The Superior Health Council has drawn up several opinions relating to the vaccination campaign. It was important to retain the link to the scientific evidence throughout the vaccination campaign and to have the flexibility to build the evidence into the vaccination strategy.

The first report on 1 July 2020 included the classification of priority persons to be vaccinated (*vaccination strategy against COVID-19 in Belgium- 9597*). The classification was based on Belgian figures relating to two endpoints: admission to ICU and death from COVID. The co-morbidities in COVID-19 patients who died or were admitted to ICU were mapped and evaluated. In addition, they took note of recent international publications. A supplement followed on 7 October 2020. At the request of the Vaccination Task Force, the Superior Health Council delivered a more detailed advisory report based on the same principles on 5 February 2021 (9618): *recommendations for prioritising subgroups of patients younger than 65 for vaccination against Sars-CoV-2*. This forms the basis for the vaccination campaign for people with co-morbidity.

Furthermore, the following opinions were published in direct relation to vaccination: opinion 962 (09-02-2021) Astra-Zenica Oxford vaccine in +65 year olds, letter opinion 9635 (02-03-2021) update vaccination Covid-19, opinion 9626 (11-03-2021): vaccination Covid-19 VVN Rep, urgent letter 1 (15-03-2021), continuation Astra-Zenica, urgent letter 2 (19-03-2021): continuation of Astra-Zenica vaccination after EMA position, urgent letter 3 (18-04-2021) redistribution AstraZenica position EMA, opinion 9622 (22-04-2021) Vaccination against Covid-19 in pregnant women, opinion 9641–9611 (23-04-2021): priorities for vaccination Phases Ib and II, letter opinion 9639 (17-05-2021) required competencies for vaccination, opinion 9634 (09-06-2021) 1 or 2 doses if infected with Sars-CoV-2 and opinion 9655 (09-07-2021) vaccination against Sars-CoV-2 from 12 years.

### 2.3. MAIN CONCLUSIONS OF ADVISORY REPORT 9618 OF 05-02-2021: RECOMMENDATIONS FOR PRIORITISING SUBGROUPS OF PATIENTS YOUNGER THAN 65 FOR VACCINATION AGAINST SARS-COV-2.

Age remains the most important risk factor for severe disease development in COVID-19 infection, leading to hospitalisation and possible death. After the +65-year-old cohort, the 18–64-year-olds cohort of people with co-morbidities were next by decreasing order of age. The report goes into detail about the criteria and, among other things, gives advice on the parameters to be followed in order to identify persons at risk, e.g. via the ATC codes of medication. For each risk factor, the publications on which the choice was based are also indicated.

The cohort aged 18-64 was divided into three priorities. For the 45-65-year-olds group, priority 1 was maintained (see table 2). For the younger group up to 18 years of age, only some of these priorities were considered to be priority 1 and the others were considered to be priority 3. Persons without co-morbidity aged 45-64 were prioritised with regard to the risk parameters: chronic pulmonary diseases, chronic cardiovascular diseases, chronic neurological diseases, diabetes type 1 and 2, malignant non-haematological diseases, obesity and hypertension. In these cases, age was more important than co-morbidity.

**Table 2: Summary co-morbidities opinion Superior Health Council 9618 (05-02-2021)**

cohort	Priority 1	Priority 2	Priority 3
<b>aged 45-64</b>	Chronic lung diseases Chronic cardiovascular diseases Chronic neurological diseases Diabetes 1 and 2 Malignant non-haematological diseases Malignant haematological diseases Chronic liver diseases Chronic kidney diseases Immuno-compromised Transplant Down's syndrome Hypertension Active HIV Rare diseases	All persons without co-morbidity	The vaccine has been offered to everyone in priority 1 or 2
<b>aged 18-44</b>	Malignant haematological diseases Chronic liver diseases Chronic kidney diseases Immuno-compromised Transplant patients Down's syndrome Active HIV Rare diseases	none	Chronic lung diseases Chronic cardiovascular diseases Chronic neurological diseases Diabetes type 1 and 2 Malignant non-haematological diseases Obesity Hypertension

Based on this report, the Vaccination Task Force decided to vaccinate the 18-64 cohort with a priority 1 co-morbidity as a priority after the +65 cohort had received the opportunity to be vaccinated.

The age limit for patients with co-morbidities was lowered to 16 in mid-May, as 16- and 17-year-olds were always included in the Pfizer and Moderna studies. During the vaccination campaign, Pfizer and Moderna received approval from the European Medicines Agency on 28 May 2021 for use in 12–15-year-olds. The same reasoning was applied to both cohorts to prioritise vaccination of high-risk patients based on the same parameters as for 18–44-year-olds.

### 3. STRATEGY OF THE SELECTION PROCESS: A COMBINATION OF CENTRAL (VI) AND DECENTRALISED (HA) SELECTION, COMPLEMENTED BY INDIVIDUAL SELECTION BY RARE DISEASE SPECIALISTS.

#### 3.1. INTRODUCTION

Eligibility for priority vaccination was determined based on the opinion of the Superior Health Council (see point 2). The challenge, however, was to identify those individuals as efficiently as possible and to invite them for vaccination as soon as possible. Technological support was developed. A legal framework was also put in place so that these individuals could be invited while respecting privacy and medical secrecy. No database in Belgium turned out to have all the exact medical information necessary. It was immediately clear that intense complementary cooperation between different information sources would be needed in the interest of every person at heightened medical risk. In order to safeguard the equity principle, the path chosen was complementary operation of central selection through the IMA and the health insurance funds and a decentralised selection through general practitioners. This approach was unique in Europe.

#### 3.2. LEGAL BACKGROUND

The vaccination campaign is legally based on the Cooperation Agreement of 12 March 2021 between the Federal State, the Flemish Community, the French Community, the German-speaking Community, the Joint Community Commission, the Walloon Region and the French Community Commission on the processing of data on vaccinations against COVID-19 (published in the Belgian Official Gazette on 9 April 2021 and which entered into force on 14 April 2021).

A cooperation is based on Article 92*bis*, §1, first paragraph of the Special Law of 8 August 1980 on institutional reform. This makes it possible for the federal government, the communities and the regions to conclude cooperation agreements 'concerning, among other things, the joint management of common services and institutions, the joint exercise of own competences, or the joint conduct of initiatives'. The Cooperation Agreement was submitted for the opinion of the Data Protection Authority (opinion 16-2021 of 10 February 2021), the "Flemish Oversight Commission" (opinion 2021/13 of 17 February 2021), the Council of State (68.832/VR, 68836/VR, 68837/VR 68.839/VR, 68.840/VR, 68/844/VR of 18 February 2021), the Flemish Council for Welfare, Public Health and Family (opinion of 16 February 2021), the inter-French-speaking consultative committee and the intra-French-speaking ministerial consultative committee (opinion of 15 February 2021).

Although the title of the Cooperation Agreement suggests otherwise, it covers not only the legal basis for the processing of data relating to COVID-19 vaccinations, but also, to a limited extent, the procedure that is followed.

It can be deduced from the Cooperation Agreement that the procedure consists of two parts:

1. the activation of a citizen's invitation to be vaccinated and the associated modalities of making an appointment;
2. the vaccination itself which is then registered in a central database. However, the practical organisation of vaccination is a matter not covered by the Cooperation Agreement. That is left to the competent authorities to regulate within their respective geographical territories.

### 3.2.1. ACTIVATION OF THE INVITATION

Article 2(1) states that any person residing on Belgian territory is first of all assigned an ad random vaccination code. Registered residence on Belgian territory is the requirement to be eligible for vaccination against COVID-19. There is no requirement to have Belgian nationality. However, residence means that the person is officially registered as residing somewhere in Belgium. De facto residence without any form of registration cannot lead to an invitation to be vaccinated.

If a citizen qualifies on the basis of this strategy, the person is selected for an invitation, so that he can make an appointment to be vaccinated or an appointment time is proposed to him. He then receives a vaccination code. Since the regional authorities are responsible for the practical organisation, in some regions individuals may have had to make an appointment themselves, while in other regions an appointment time may have been proposed by the vaccination centres.

When a person is selected for an invitation to be vaccinated in accordance with the vaccination strategy adopted by the competent authorities and wishes to make a vaccination appointment or is offered an appointment time, the vaccination code allocated to that person is communicated to him for this purpose.

The Cooperation Agreement does not define the order in which population groups are vaccinated. It leaves this to the competent authorities according to their vaccination strategy. The determination of which persons are to be vaccinated as a priority is made by the Interministerial Conference on Public Health on the basis of the recommendations of the Superior Health Council and the Vaccination Task Force. The prioritisation rules may evolve over time in the light of evolving science and available vaccines. Comprehensive and constantly updated information on this subject is available on the Sciensano portal in Dutch, French and German (<https://COVID-19.sciensano.be/nl/COVID-19-vaccinatie>).

However, the Cooperation Agreement provides for the selection to be made:

#### 3.2.1.1. ON THE BASIS OF AGE.

If prioritisation does not occur on the basis of age, it occurs on the basis of the information from the National Register or the Crossroads Bank registers.

#### 3.2.1.2. ON THE BASIS OF STATE OF HEALTH

Although the Cooperation Agreement explicitly mentions selection on the basis of state of health, this selection does not take place in the Vaccination Codes database. Whether a person's state of health justifies priority vaccination is assessed either by the health insurance fund to which the person is affiliated, based on the available information on reimbursed healthcare, or by a doctor who has a care relationship with the person, based on the patient's health record (Electronic Medical Record). If a health insurance fund or a doctor who has a care relationship with the person concerned considers, on the basis of the information about state of health, that the person in question is eligible for priority vaccination, this fact is noted in the Vaccination Codes database, without any grounds being given. Thus, no health data of any substance is included in the Vaccination Codes database, but only the fact that the person should be invited for vaccination as a matter of priority on the basis of an evaluation of his state of health by the health insurance fund or a doctor.

The Cooperation Agreement explicitly states that if this selection requires certain information to be provided by the attending physician, this is permitted. This indication is necessary in order to constitute a justified restriction on the doctor's professional secrecy, which is protected under criminal law (Article 458 of the Criminal Code). Please note that the Cooperation Agreement only mentions the 'attending physician'. Other healthcare professionals, who are also bound by professional secrecy, cannot

justifiably share this information. Moreover, the Cooperation Agreement speaks of the 'attending' physician. Consequently, not every doctor who has access to a patient's health data is allowed to make it available. This derogation from professional secrecy is in no way intended to disclose the exact nature of the state of health that makes a person's vaccination a priority. Only the information that the person is eligible due to his state of health may be communicated. This communication never states, for example, that a person has diabetes, but only that a person needs to be vaccinated as a priority due to his state of health.

Article 9(2)(i) of the General Data Protection Regulation can be invoked for all the processing operations carried out with the information system, as the processing operations are part of the fight against a pandemic.

### 3.2.1.3. ON THE BASIS OF OCCUPATION AND/OR PLACE OF EMPLOYMENT

If priority vaccination is done on the basis of profession or place of employment, the selection is made on the basis of a database made available by the Federal State (such as NSSO or Cobhra), the federated entities or the employer.

## 3.2.2. REGISTRATION IN VACCINNET

In accordance with Article 2(2), vaccinations against COVID-19 are recorded in Vaccinnet by the person who administered the vaccine or under whose supervision the vaccination took place. The person who administered the vaccine or under whose supervision the vaccination was carried out may also delegate the registration in Vaccinnet to an authorised person, who will carry out the registration in Vaccinnet under his responsibility. This authorised person (including the medical administrative staff) is bound by a duty of discretion. Please note that a duty of discretion is not the same as professional secrecy. A duty of discretion allows this information to be shared with the authorised person's supervisors, for example.

Vaccinnet is the registration system of vaccinations per person. Although Vaccinnet is a Flemish initiative, it is referred to in the Cooperation Agreement as the common information system used by Flemish, Brussels, Walloon and German-speaking vaccinators. A common information system is necessary for, among other things, optimal crisis management, pharmacovigilance, tracking the population's vaccination coverage and the impact on health insurance. However, Article 10 of the Cooperation Agreement stipulates the possibility of migrating all data from this database to another centralised database if all signatories to this Cooperation Agreement agree. To date, this has not been done.

The use of Vaccinnet with respect to COVID-19 vaccines shall be in accordance with the provisions of this Cooperation Agreement.

## 3.2.3. 3 DATA PROCESSING

The main purpose of the Cooperation Agreement is to enable the processing of personal data necessary to send vaccination invitations and to monitor the vaccinations carried out.

### 3.2.3.1. PERSONAL DATA IN THE VACCINATION CODE DATABASE

The Cooperation Agreement strictly defines the categories of data recorded in a Vaccination Codes database, hosted in the federal G-Cloud and jointly managed by the federated entities responsible for the organisation of vaccination and Sciensano. These categories include for each vaccination code allocated, the identity details of the

person to whom the vaccination code is allocated, the assigned meaningless vaccination code, information on the status of the meaningless vaccination code, if applicable a reference to the type of vaccine, the date of administration and the schedule for vaccination as well as, if relevant, the indication of which type of vaccine may be administered to the person.

Finally, it also relates to contact details, which, if available, are obtained from healthcare providers, insurance institutions and the CSAM authentication service. These data are necessary to enable efficient invitations and to avoid wastage of vaccines, so that last minute invitations can be issued.

The Vaccination Codes database does not contain medical data, except for the indication of vaccination status. In order to avoid indirectly revealing information about a person's state of health just by being included in the database, each person is assigned a vaccination code. The vaccination code is activated for a person invited for vaccination only if the source that selected the person does not administer the vaccine itself. An active vaccination code allows the person concerned or the vaccination centre to reserve one or two vaccination time slots at a vaccination centre. If the source of the selection does not administer the vaccine itself, the selection leads to the activation of a vaccination code for the person in the Vaccination Codes database. A vaccination code is not activated if the person has already been vaccinated against COVID-19.

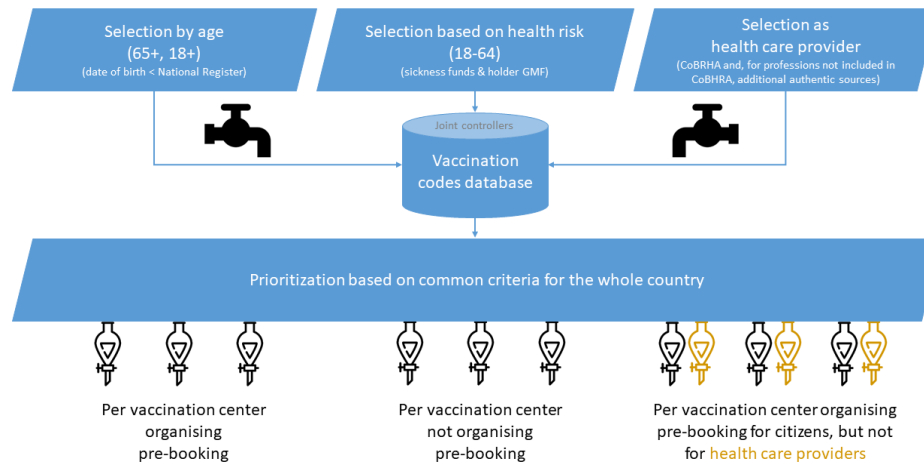
A person selected for a vaccination invitation may be deselected by his attending physician if contraindications for the vaccination exist. In that case, the vaccination code is deactivated in the Vaccination Codes database. A person who refuses to be vaccinated can also deselect himself from the Vaccination Codes database.

If the vaccination code is deactivated after the first dose of vaccine and before the second dose, no second vaccination will take place until the code is reactivated electronically on request of the person concerned (or via his GP or GMD holder).

These data are kept in this first database for a maximum of 5 days after the day of publication of the Royal Decree declaring the end of the epidemic.

These data from the Vaccination Codes database may be processed for the following purposes:

1. management of COVID-19 vaccination schedules per person vaccinated or to be vaccinated and the scheduling of vaccination times, including by the vaccination centres and healthcare providers;
2. inviting and offering support in the invitation process, of persons to be vaccinated against COVID-19 by healthcare providers, insurance companies, vaccination centres, the federal government, competent federated entities and local authorities;
3. the logistical organisation of the vaccination against COVID-19, after anonymisation of the data or at least pseudonymisation of the data if anonymisation would not allow the logistical organisation to be realised.
4. feedback to the electronic patient file, which also feeds the vaccination barometer

**Figure 3: algorithm prioritisation via the Vaccination Codes database**



### 3.2.3.2. PERSONAL DATA IN VACCINNET

The details of a vaccination recorded in Vaccinnet are also strictly defined: details of the person vaccinated, of the person administering the vaccine (who must be able to be warned of any undesirable effects), of the vaccine, of the circumstances surrounding the administration of the vaccine, of the COVID-19 vaccination schedule of the person to whom the vaccine is administered and, if necessary, of any undesirable effects of the vaccine (on-site or at home).

the data on possible undesirable effects is only available in Vaccinnet on an optional basis at the time of vaccination and not for pharmacovigilance purposes. This is without prejudice to the obligation to keep records of any serious undesirable effects of the vaccination observed during or after the vaccination of the person concerned that the person who administered the vaccine or his authorised representative knows about or should know about. These undesirable effects are registered directly in the Vigilance Online Notification System. The GP's GMD also contains a direct link to register side effects.

The use of the unique identification number (national register number) is absolutely necessary in this framework, since the vaccination status must be able to be linked to a person at all times in an unambiguous way and contains crucial information for quality care provision. Unambiguous identification of a person who is vaccinated or to be vaccinated is crucial for correct vaccination and follow-up. The unique number is the cornerstone of all electronic data exchanges in that framework; otherwise, no unambiguous identification of the healthcare user is possible and (medical) errors could be made. Finally, a unique identification makes it possible to recall certain batches of a vaccine quickly in the event of problems.

In addition, the use of a unique identification number per healthcare user throughout the Belgian health information systems is imposed by Article 8 of the Act of 21 August 2008 on the establishment and organisation of the eHealth platform. This Cooperation Agreement and the Act of 21 August 2008 contain measures to cope with the risks associated with the use of a unique identification number.

The place where the vaccine is administered does not refer to the exact address, but to whether, for example, the vaccination is administered at a general practitioner's office, at a particular company, at a particular entity or at a particular vaccination centre. This is useful, for example, to determine vaccination coverage within companies or collectivities, or to be able to go back to relevant circumstances of vaccination in the case of an ineffective vaccine. It also, for example, allows the person to be vaccinated at the correct vaccination site for successive doses with a view to better follow-up.

This data can be processed for the following purposes:

1. the provision of healthcare and treatment, as referred to in Article 9(2)(h) of the General Data Protection Regulation, which is exclusively aimed at vaccination and support, information and awareness-raising measures for citizens with regard to vaccination;
2. the pharmacovigilance of the vaccines against COVID-19, in accordance with Article 12sexies of the Act of 25 March 1964 on medicines and the detailed guidelines published by the European Commission in the "Module VI – Collection, management and submission of reports of suspected undesirable effects to medicines (GVP)", as laid down in the latest version available, and as referred to in Article 4, paragraph 1(3) of the Act of 20 July 2006 on the establishment and functioning of the Federal Agency for Medicines and Health Products;
3. the traceability of the vaccines against COVID-19 in order to ensure the follow-up of "rapid alerts of vigilance" and "rapid alerts of quality" as referred to in Article 4(1), section 3, paragraph 3(e), and paragraph 4(j) of the Act of 20 July 2006 on the establishment and operation of the Federal Agency for Medicines and Health Products;

4. the management of schedules for vaccination against COVID-19 per person vaccinated or to be vaccinated and the scheduling of vaccination times, including by the vaccination centres;
5. the logistical organisation of the vaccination against COVID-19, after anonymisation of the data or at least pseudonymisation of the data in case anonymisation would not allow the logistical organisation;
6. to determine vaccination coverage against COVID-19 among the population anonymously;
7. to organise contact tracing in implementation of the Cooperation Agreement of 25 August 2020 between the Federal State, the Flemish Community, the Walloon Region, the German-speaking Community and the Joint Community Commission, concerning the joint processing of data by Sciensano and the contact centres, health inspectorates and mobile teams designated by the competent federated entities or by the competent agencies within the framework of a contact tracing of persons (presumed) to be infected with the COVID-19 coronavirus, based on a database at Sciensano;
8. to carry out post-authorisation monitoring and surveillance of the vaccines in accordance with best practice recommended by the World Health Organisation, after anonymisation of the data or at least pseudonymisation of the data in case anonymisation would not allow post-authorisation monitoring and surveillance;
9. without prejudice to the regulations on health insurance, the calculation of the distribution of the cost of vaccination between the Federal State and the federated entities, after anonymisation of the data or at least pseudonymisation of the data in the event that anonymisation would not allow the calculation of the distribution;
10. to carry out scientific or statistical studies, in accordance with Article 89(1) of the General Data Protection Regulation and, where applicable, Article 89(2) and (3) of the General Data Protection Regulation and Title 4 of the Act of 30 July 2018 on the protection of individuals with regard to the processing of personal data, after anonymisation, or at least pseudonymisation, in the event that anonymisation would not allow the scientific or statistical study to be carried out;
11. to inform and raise awareness among people about COVID-19 vaccination by healthcare providers and insurance institutions.

### 3.2.4. VACCINATION OF MINORS

During the vaccination campaign, the question of how the vaccination of minors should be approached from a health law perspective was raised.

#### 3.2.4.1. PRINCIPLE PATIENTS' RIGHTS ACT

The Act of 22 August 2002 on the Patients' Rights is based on the individual treatment relationship (= contractual or non-contractual private or public law legal relationship, Art. 3) between a patient and a healthcare provider. Every patient independently exercises all of their patient's rights as described in this Act. This includes the right to informed consent for any intervention (Art. 8).

A right to informed consent can be either written, oral or tacit (Art. 8(1), para. 2). Tacit consent means that the healthcare provider, after having adequately informed the patient, may infer the patient's consent from the patient's behaviour (e.g. the patient comes to the vaccination centre, presents himself and once in the practice room rolls up his sleeve so that the healthcare provider can administer the vaccine). All three forms of consent are legally equally valid.

The law stipulates that, at the request of the patient or the professional and with the agreement of the professional or the patient, the consent must be recorded in writing and added to the patient file (Art. 8(1), para. 3).

#### 3.2.4.2. REPRESENTATION OF AN UNDERAGE PATIENT

The principle that every patient exercises their patient's rights independently does not apply if the patient is a minor (under 18 years of age).

These patients' rights are exercised by the parents who have custody of the minor or by the minor's guardian (Art. 12(1)). They represent the underage patient in the exercise of his patient's rights.

With regard to an underage patient, it is the parents or guardian who must consent to vaccination. Again, oral, written and tacit consent are all valid. In this context, tacit consent means that the parents bring the child to the vaccination centre and accompany him until the vaccination is administered. A written consent is not required but can also be requested in this case.

The minor should be involved in the exercise of his patients' rights, taking due account of his age and degree of maturity (Art. 12(2), first sentence).

#### 3.2.4.3. MEDICAL MAJORITY OF AGE

In line with the principle that every patient exercises his patient's rights independently, but as an exception to the fact that the parents as representatives exercise the rights of the underage patient, the Patients' Rights Act provides for the concept of medical majority of age (Art. 12(2), last sentence).

Medical majority means that an underage patient who is deemed capable of making a reasonable assessment of his interests exercises his patient's rights independently. It follows from the legal relationship between the patient and the healthcare provider covered by the Patient's Rights Act that the healthcare provider considers whether the underage patient can be regarded as medically of age.

However, the Patients' Rights Act must be interpreted in the spirit of the times of 20 years ago. Today, healthcare is provided by a multidisciplinary team of healthcare providers. And as part of the vaccination campaign for a very large group of patients.

Since the law is insufficiently adapted to the context of this vaccination campaign, one should not be blind to the fact that, strictly speaking, although it is the healthcare provider who does the weighing up of medical majority of age, the government can formulate guidance in this respect. Moreover, the possibility of government intervention is explicitly provided for in Article 3. The King, after consultation in the Council of Ministers and after advice from the Federal Commission on Patients' Rights, retains the power to determine further rules on the application of the law to the aforementioned legal relationships, in order to take into account the need for specific protection.

The government has taken the position that underage patients aged 16 and 17 can be considered medically of age in the context of this vaccination campaign, as long as they have been sufficiently informed through various channels and have been able to ask questions for clarification.

Once the minor is considered to be medically of age, the principle contained in the Patients' Rights Act that each patient exercises his rights as a patient independently prevails again. The minor may therefore give his own consent to vaccination. Since the parents are no longer acting as representatives at this point, they can no longer give their consent, nor are they required to agree with the minor's decision. Again, the consent can be given in writing, orally or tacitly. However, the fact that the parents can no longer give their consent does not imply that they cannot actually be involved in the exercise of patients' rights by the (medically adult) minor. This is not a legal principle, however. Rather, it merely follows from the normal course of events.

The CLB recommends, in the context of the vaccinations it carries out, that a consent form be signed by the parents. However, the final assessment of whether vaccination can take place is based on the principles of the Patients' Rights Act. The use of a written consent, however, creates the false impression that the parents may still consent even in the case of a medically adult patient. To avoid this appearance of consent, it is not recommended to work with a parental consent form. There should be efforts at an earlier stage to involve the parents in informing the (medically adult) minor.

#### 3.2.4.4. CONFLICT

If the parents/guardian and the child do not agree on the administration of the vaccine, the following scenarios may occur:

##### **Parents want vaccination, child does not**

The vaccine is not administered. The underage patient may refuse consent to the vaccine as a medical adult. The underage patient's refusal should not be considered as proof that the underage person is not yet capable of making a reasonable assessment of his interests.

If the underage patient cannot yet be considered as "medically of age", he cannot be required to be vaccinated by force. The underage patient must always be involved in the exercise of his patient's rights, taking into account his age and degree of maturity. This implies that he may not be obliged to receive the vaccine.

##### **Parents do not want vaccination, but the child does**

If the parents do not want their child to be vaccinated, but the child does, strictly speaking there is no conflict under the terms of the Patients' Rights Act. The underage patient may independently exercise his patient's rights. The parents no longer represent the child and cannot intervene.

In practice, however, this would lead to a conflict that may put the family under strain. It is thus appropriate for a third party, preferably the general practitioner, to act as a confidant in an attempt to avoid the potential conflict.

In the context of vaccinations via the CLB, it is recommended that written confirmation of the underage patient's consent be obtained. This can then be endorsed.

##### **Parents do not agree with each other**

This situation only arises in the case of a child who cannot yet be considered capable of making a reasonable assessment of his interests and where the parents are acting as the child's representatives.

In case of disagreement between the parents, the care provider (general practitioner, paediatrician, etc.) will attempt to mediate. If no solution can be found: Then the juvenile court will make a decision in the best interest of the underage patient as to whether the vaccination should take place or not.

### 3.3. SELECTION

Three selection procedures were used to detect high-risk individuals: a central selection via national databases, a decentralised selection via the GMD-holding GP and a complementary selection, aimed at specific target groups, via GPs and specialists.

#### 3.3.1. CENTRAL SELECTION

##### 3.3.1.1. STARTING POINTS.

The intention of the central selection was to conduct a broad initial selection in order to capture as many people as possible with a risk profile, including those who do not have a GP or GMD doctor, for example. This was important because of regional differences, including as regards GMDs. The IMA holds the billing data for the reimbursed healthcare of all mutual health insurance companies in pseudonymised form. The medical condition of a person can be indirectly deduced from this enormously extensive database. The selection criteria set for priority 1 (see table 2) by the Superior Health Council were translated into search algorithms for billing data. Due to this indirect approach, the selection could not be carried out with surgical precision. However, not selecting a person at risk due to strict parameters was considered a more serious error than including a non-risk person in the priority group for vaccination. Thus, the selection parameters were interpreted broadly. After the selection, the CIN was able to link the pseudonymised data to national register numbers.

##### 3.3.1.2. SOME OF THE LIMITATIONS OF THIS CENTRAL SELECTION.

As mentioned above, no database in Belgium contains the exact information. Since the IMA database only contains billing data, we encountered some limitations:

- The IMA's data collection lagged behind the actual provision date. At the time of selection (2 April 2021), the IMA data were complete up to 31 December 2020. Persons who did not meet the selection criteria until 2021 were not detected by this central selection.
- It was not possible to use billing data to identify patients with cancer. Too great an inaccuracy would have arisen as the Superior Health Council attached different priority to haematological and solid tumours. It was therefore necessary to work with an exact diagnosis for this group. For this purpose, the Cancer Registry Foundation was called in to make the necessary selection.
- Only seropositive HIV patients with active disease were deemed to be high-risk patients. The IMA database does not contain laboratory results. Therefore, for this group, it was decided to use only decentralised selection by the general practitioner.
- A BMI cannot be determined from the IMA database. For obese patients, selection was conducted on a decentralised basis by general practitioners. However, persons who underwent a reducing gastropasty or required respiratory support due to their obesity could be centrally selected due to the accuracy of this parameter. A significant proportion of obese patients were also (indirectly) centrally captured by a co-morbidity such as hypertension, diabetes ...
- People with rare diseases (with the exception of mucoid patients) have too few specific bills to indirectly infer the condition. For these small groups, a complementary registration by specialists was done via a web application in the hospitals that intensively monitored these persons.

- The IMA database's billing data is not specific enough to identify individuals with Down's syndrome. The results of chromosome determinations are not included in the billing data. For these people, too, the decision was taken to conduct selection decentrally by general practitioners only.

### 3.3.1.3. THE TRANSLATION TO PARAMETERS APPLICABLE TO BILLING DATA

In the following table, the selection criteria for priority 1 under the Superior Health Council's advice (see table 2) are translated into parameters that can be found in billing data. With these parameters, a query was applied to the IMA database to obtain the selection cohort.

**Table 3: translation of co-morbidities into algorithms for billing data**

Co-morbidity	age	Search period: 31/12/2020	x- Invoicing data/nomenclature
Chronic lung disease	45-64	18 months	Purchase of medication ATC code R03 (min 90 DDD) Invoice chronic oxygen use Invoice ventilation Invoice sleep apnoea treatment via cPAP Invoice respiratory rehabilitation Invoice nomenclature restrictive lung surgery Invoice nomenclature Kine E pathology
		60 months	Invoice of lung function test (twice a year)
		12 months	Purchase of medication at least two products (90 DDD) with ATC code: A09AA02 R05CB01 R05CB13 J04AB04 J01GB01 J01XB01
Chronic cardiovascular diseases	45-64	18 months	Purchase of medication with ATC codes: C01 C05 C08 C09 C10 (vasoprotectives, b blockers, ca channel blockers, renin angiotensin antagonists and hypolipaemic medication) at least 90 DDD Invoice cardiac rehabilitation
		60 months	Invoice nomenclature surgery large blood vessels Invoice nomenclature cardio surgery Invoice locomotor rehabilitation other than group B4
Chronic neurological diseases – dementia	45-64	12 months	Invoice purchase of medication with ATC code (90 DDD) L04AA31, L03AX13, L03AB07, L03AB13, L04AA34

			Speech therapy invoice for aphasia, dysarthria and chronic speech disorder in neuromuscular diseases, Parkinson and MS. Invoice locomotor rehabilitation other than group B4 Invoice rehabilitation in memory clinics, minimum 4 times Invoice rehabilitation in a neuromuscular reference centre Invoice multidisciplinary rehabilitation i.a. NAH problems
		60 months	Invoice purchase of medication with ATC code (90 DDD) N06DA04, N06DA03, N06DA02
<b>Diabetes 1 and 2</b>	45-64	12 months	Invoice purchase medication with ATC code (90 DDD) A10 Invoice diabetes pre-trajectory and diabetes care trajectory Invoice diabetes convention (type 1 and 2 diabetes under insulin therapy, with or without pump, continuous glucose monitoring or sensor)
<b>Obesity</b>	45-64	12 months	Invoice respiratory support for hypoventilation due to obesity Invoice nomenclature reduction gastroplasty
<b>Malignant non-haematological disorders</b>	45-64	60 months	Cancer registry based on anatomopathological report
<b>Malignant haematological disorders</b>	18-64	60 months	Cancer registry based on anatomopathological report
<b>Chronic liver diseases</b>	18-64	18 months	Invoice medication with ATC code (90 DDD) A06AD11
<b>Chronic kidney diseases</b>	45-64	12 months	Invoice medication with ATC code (90DD) V03AE, A11CC03 Invoice nomenclature care pathway chronic renal insufficiency
	18-64	12 months	Invoice medication with ATC code (from 1 DDD) B03XA01 Invoice nomenclature of haemodialysis in any form
<b>Immuno-compromised</b>	18-64	12 months	Invoice medication with ATC code (from 1 DDD) L04A
<b>Transplant patients</b>	18-64	60 months	Invoice HLA typing when registering on the Eurotransplant list Invoice stem cell transplantation Invoice nomenclature organ transplantation Invoice nomenclature bridge-to-transplant or bridge-to-decision
<b>Hypertension</b>	18-64	12 months	Invoice medication with ATC code C02, C03, C07



Rare diseases	18-64	1 year	Purchase of minimum 2 medications (90 DDD) with ATC code A09AA02, R05CB01, R05CB13, J04AB04, J01GB01, J01XB01, J01XB01 Invoice from a muco reference centre Invoice locomotor rehabilitation (B4)
Down's syndrome	18-64		No data in central selection
Active HIV	18-64		No data in central selection

### 3.3.1.4. THE CENTRAL SELECTION PROCEDURE

On the basis of the coordinated ZIV Act of 14 July 1994, the mutual health insurance companies must have medical information at their disposal in order to guarantee their work as paying agents and to exercise control. They are also the absolute endpoint for this information to ensure privacy and the protection of medical confidentiality. The legal prerequisites for carrying out the central selection had to be carefully met first (see legal aspects also). After all, the process involved transferring indirect medical data to a public authority without the explicit consent of the persons concerned. The R.D. of 24 December 2020 on the registration and processing of data relating to vaccination against COVID-19 provides the legal framework. The Cooperation Agreement with the various governments was signed last by COCOM (Brussels) on 2 April 2021. Meanwhile, the Information Security Committee issued a favourable opinion on 8 February 2021 on the various information flows and a favourable opinion from the Data Protection Authority on 10 February 2021. The latter cites the vital importance of the vaccination campaign to the population. This obliges the insurance institutions to pass on the selection. The individuals' consent is not required. The insurance institutions cannot delete persons who have been selected. However, the person concerned has a right of inspection; he should be able to find out whether he is part of the selection. As part of the Cooperation Agreement, an assignment letter was signed by Flemish Minister of Public Health Wouter Beke, as chairman of the Interministerial Conference on Public Health on 12 March 2021.

The central selection was implemented in *one shot* on 2 2021. The Cancer Registry transferred its selection of high-risk patients to the NIC on the basis of national register numbers. The IMA applied the above query to its data warehouse and the obtained selection of pseudo-anonymised data was linked to the national register number by NIC. The NIC processing split the list by insurance institution based on the authentic source "NIC-Filter" (with connection to the health insurance funds). The specific list per insurance institution was securely transmitted to the medical directorate of the corresponding insurance institution. In this way, medical confidentiality was respected through the authority of the medical director.

After receiving the *go* from all the medical directors of the insurance institutions, the NIC transferred the list to the Vaccination Codes database to activate the corresponding codes and give the parameter for the type of vaccine. The identity of the activation partner (here NIC) was also stored in the Vaccination Codes database.

### 3.3.1.5. RESULTS OF THE CENTRAL SELECTION

In total, a cohort of 1,154,957 individuals were selected as having high-risk co-morbidities and activated for priority vaccination. This was the distribution among the different age categories:

**Table 4: cohort central selection persons with co-morbidities**

Category	Age range	number	Total population	% persons at risk
18-44 y/o	18-24 y/o	3085	925458	0.33
18-44 y/o	25-29 y/o	3932	739469	0.53
18-44 y/o	30-34 y/o	5317	743369	0.72
18-44 y/o	35-39 y/o	6690	748921	0.89
18-44 y/o	40-44 y/o	8356	736872	1.13
45-64 y/o	45-49 y/o	152802	767667	19.90
45-64 y/o	50-54 y/o	235959	790892	29.83
45-64 y/o	55-59 y/o	333821	799736	41.74
45-64 y/o	60-64 y/o	404995	723739	55.96
<b>totals</b>		1,154,957	6,976,123	16.56

From 4 April 2021 onwards, these people could be invited for vaccination as a priority, by decreasing order of age. At that time, the speed of invitations for vaccination was determined primarily by vaccine availability, the capacity of vaccination centres, and the vaccination coverage of the previous cohort (those over 65). At that time, Flanders was still working on the 70-74 age category and invited the first high-risk individuals in the fourth week of April 2021. Brussels and Wallonia advanced through the age groups more quickly due to lower vaccination coverage compared to Flanders. In Brussels, the younger age structure of the population also played a role. This allowed those at risk in Wallonia and Brussels to be invited for vaccination in the first week of April. This was also the case for the German-speaking community. The decentralised selection by general practitioners started on 13 April 2021 (see section 3.5)

To ensure the right of access, each person was able to view their personal selection and vaccination status at [www.myhealthviewer.be](http://www.myhealthviewer.be). There was a supplementary circuit via the mutual health insurance companies for people who could not find the necessary information via myhealthviewer. Some health insurance officers were able to inform members about the selection and their vaccination status, under delegation from the medical director. This was to ensure both patient's rights and medical confidentiality.

In order to minimise the vulnerability of the selection to fraud, employees of the insurance companies were not able to add or delete additional persons to the *one shot* central selection. GPs, on the other hand, had both options available to them.

### 3.3.2. DESCRIPTION OF THE DECENTRALISED SELECTION

#### 3.3.2.1. PRINCIPLES AND METHOD

The electronic medical record (EMD) of GMD-holding general practitioners is the most comprehensive source of medical information in our healthcare system. If the EMD is well managed by the GP, it is an ideal source to identify people at risk. However, the bottleneck in this strategy is data completeness (structured and coded) of the EMD.

The EMD allows an electronic search to be carried out in the GP's patient file. This allows high-risk patients to be identified on the basis of structured and coded data in their records. Moreover, such *queries* can identify diagnoses that have not been coded: for example, a patient without the coded diagnosis of hypertension can be identified by a number of elevated blood pressure measurements. GPs can develop such *queries* themselves in their EMD using the statistics module. The EMD developer can also develop these electronic searches centrally for all users, standardised and automated. This method was chosen for the decentralised selection of people with co-morbidities. The advantage of this strategy is, firstly, that you have much more flexibility and are less limited in the design of the queries. Secondly, this way you achieve uniform results that all users perform in the same way at the *touch of a button*. The bottleneck is that there are eight EMD developers in Belgium. Not every EMD is designed in the same way, so the queries have to be translated to every EMD programme. This also means that there can sometimes be differences between the EMD systems according to the output of the survey.

Together with Bemeso and Agoria, the organisations representing the EMD developers, a plan was drawn up in January 2021 to make the necessary developments in the EMD systems. This would allow GPs to play their part in the COVID-19 vaccination strategy.

The development process consisted of 3 steps:

1. the development of a diagnostic tool to help general practitioners register their high-risk patients correctly;
2. the development of queries to identify high-risk patients and load their selection into the Vaccination Codes Database (VCDB)
3. the development of a tool (vaccination barometer) to monitor vaccination coverage in their own practice (see 3.9).

In order to realise these developments quickly, it was agreed with the RIZIV and eHealth that the homologation requirements for the EMD systems would be temporarily put *on hold* until the end of April 2021.

In order to make the requested developments within the EMD systems as uniform as possible, a weekly consultation was held between GPs, EMD developers, and representatives of Bemeso and Agoria. The planned developments and the communication strategy towards the users were discussed. In addition, eHealth and the EMD developers regularly discussed the connection (API) between the EMD systems and the VCDB.

### 3.3.2.2. THE DIAGNOSTIC TOOL

The diagnostic tool was implemented in the EMD systems on 15 February 2021. It contained four queries that allowed GPs to identify potential high-risk patients who were not yet correctly registered in their EMD. These were queries for diabetes mellitus, chronic renal insufficiency, chronic lung disease and chronic cardiovascular disease. Using *proxies* for these conditions (haemoglobin A1C and glycaemic values and medication for diabetes, eGFR values for renal insufficiency and medication for pulmonary and cardiovascular conditions), patients were identified who may have had these conditions but had not yet been given an ICPC-coded diagnosis. In this way, the available medical information was given structure. The quality of Sumehrs<sup>e</sup> also improved. In addition, GPs were provided with information on the high-risk patients who were eligible for a priority COVID-19 vaccination. They were encouraged to correctly record patients' weight, BMI and conditions as much as possible.

### 3.3.2.3. SELECTION QUERIES CO-MORBIDITIES

The second step was the development of queries to identify high-risk patients for priority vaccination. Two queries were developed: a query to identify group 1 high-risk patients and a query to identify group 3 high-risk patients. Patients with chronic mental illnesses and socially vulnerable patients were also included among the group 1 high-risk patients. On 2 April 2021, the query for group 1 was made available to GPs. At the touch of a button, a general practitioner could identify high-risk patients and with a second touch upload the data of the selected high-risk patients into the VCDB. The EMD did not communicate any medical information to the VCDB, only the national register number. In the week of 3 May 2021, the query for group 3 was made available to GPs.

In addition to the automated queries to identify and select high-risk patients for priority vaccination, GPs could also upload individual patients as high-risk patients into the VCDB from 2 April 2021. Sometimes a patient was not identified by the automated query but still had to be considered a high-risk patient. This could occur when the patient's condition was not correctly recorded (coded), the patient did not have a Global Medical Record (GMD) with the GP but had a therapeutic relationship with the GP, or the patient had a condition that was not included in the automated query (e.g. a very recent condition). In April, pregnant women also became eligible to be referred to the VCDB as high-risk patients (see below). The latter application was implemented together with the query for group 3 in the first week of May 2021.

General practitioners were informed about the new possibilities in their EMD in two ways. On the one hand, Domus Medica organised webinars in Flanders together with the EMD developers. The webinar lasted an hour: half an hour of general explanation of the procedures and concepts and half an hour of specific *hands-on* explanation within each EMD package. On the other hand, the EMD developers sent communications about the new developments to their users, together with manuals and educational material.

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<sup>e</sup> Sumehrs = summarised electronic health record = electronic summary of the medical record containing the minimum information a doctor needs to assess your state of health. This way, a doctor who does not know your medical history can quickly provide you with the appropriate care.

### 3.3.3. DATA ON THE COURSE OF THE DECENTRALISED SELECTION PROCESS.

#### 3.3.3.1. THE DIAGNOSTIC TOOL

From the Intego database, we can document the impact of the diagnostic tool on the registration of diabetes mellitus, chronic kidney disease, chronic lung disease and chronic heart disease. We can show the relative difference<sup>f</sup> of the number of new registrations (existing and new cases) for these diagnoses between early February 2021 and May 2021 compared to the same periods in the years before the COVID pandemic.

#### 3.3.3.2. THE SELECTION QUERIES CO-MORBIDITIES

The weekly figures for the number of high-risk patients who were uploaded by GPs in the VCDB (see also the distinction between patients who were uploaded only by GPs and by mutual health insurance companies and GPs).

#### 3.3.3.3. PARTICIPATION IN THE WEBINARS ORGANISED BY DOMUS MEDICA

- Webinar vaccination barometer 16-06: 205
- Webinar vaccination barometer 28-04: 135
- Webinar: selection of high-risk patients 24-03: 648
- Webinar: audit tool 04-02: 316
- Webinar: audit tool 02-02: 414

### 3.3.4. ADDITIONAL SELECTION, AIMED AT SPECIFIC (SUB)TARGET GROUPS

#### 3.3.4.1. INTRODUCTION

The synergy between the central and decentralised selection worked strongly. However, additional adjustments were still necessary in order to be able to respond in a timely manner to advancing insight and the latest scientific data. Additional circuits guaranteed that no one entitled to a priority vaccination would miss out (*'leave no one behind'*).

#### 3.3.4.2. PERSONS WITH A RARE DISEASE

There is often little information in primary care about people with rare diseases, who are often treated in a very specific specialist way in tertiary care. Their billing records with the health insurance funds are also too unspecific to be able to detect them among the IMA data. Neither central nor decentralised selection offered a solution here.

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<sup>f</sup> This is limited to the number of group practices (n= 104) working with CareConnect as an EMD and already labelled as 'good' registrars from previous initiatives.

An additional system was set up with reference doctor-specialists in each hospital. A web application was created for them to activate these persons in the Vaccination Codes database.

### 3.3.4.3. PREGNANT WOMEN

The Superior Health Council's opinion regarding priority vaccination for pregnant women was released in the course of the vaccination campaign. Pregnant women cannot be accurately identified from the IMA's billing records but are often known in primary care. An additional selection option was added to the GPs' software packages so that GPs could manually activate these patients. Women who were only treated by gynaecologists were referred to a general practitioner for activation in the Vaccination Codes database.

### 3.3.4.4. IMMUNE-COMPROMISED PERSONS.

On 17 August 2021, the KCE published the report: *rapid review of the evidence on a COVID-19 booster dose after a primary vaccination schedule*. The report contains a thorough evaluation of breakthrough infections in vaccinated patients, both domestically and internationally, leading to the following recommendation:

'With current knowledge, selective use of an extra/booster mRNA dose (even from a few months after basic vaccination) seems sensible in immuno-compromised individuals:

- Patients with congenital immune disorders
- Patients on chronic renal dialysis
- HIV patients (CD4 T-cells <200 cells per mm3)
- Patients with blood cancer or other malignant tumours who have been on active treatment in the past few years
- Stem cell transplant and organ transplant patients
- Patients with inflammatory diseases treated with immuno-suppressants'

On 24 August 2021, the Superior Health Council confirmed the recommendations of this report in an opinion.

On 31 August 2021, Minister Wouter Beke, as chairman of the IMC (Interministerial Conference), instructed the mutual health insurance companies to carry out the selection so that immuno-compromised persons could be invited for an extra dose. The Information Security Committee (ISC) gave its approval on 7 September 2021. Once again, a complementary mechanism was chosen between a central selection via IMA and a decentralised selection by GPs.

The central data extraction of the following groups by the IMA was conducted on the basis of data up to 31 March 2021 for every person aged 12 or older on 1 August 2021.

- Patients with congenital immune disorders treated with immuno-stimulants;
- Patients on chronic kidney dialysis (any form of dialysis);

- Patients with blood cancer or other malignant tumours, who are or have been on active chemotherapy treatment in the last 3 years;
- Stem cell transplant, organ transplant patients, pre-transplant patients;
- Patients with inflammatory diseases treated with immuno-suppressants.

The translation of these parameters into billing data led to the following search strategies:

**Table 5: translation into billing data for the selection of immuno-compromised persons**

co-morbidity	period	age	Parameter
<b>Malignant neoplasia</b>	31-03-2018 to 31-08-2021	From 12 years of age	Cancer Registry based on anatomopathology
<b>Haematological neoplasia</b>	31-03-2018 to 31-08-2021	From 12 years of age	Cancer Registry based on anatomopathology
<b>Immunosuppression (not HIV)</b>	31-03-2020 to 31-03-2021	From 12 years of age	Invoice purchase of medication with ATC codes: L04AA31, L03AX13, L03AB07, L03AB13 L04AA34 (for a minimum of 90 DDD)
<b>Chronic kidney dialysis</b>	31-03-2020 to 31-03-2021	From 12 years of age	Invoice haemodialysis in any form
<b>Pre-transplant and transplant patients</b>	31-03-2016 to 31-03-2021	From 12 years of age	Invoice HLA typing at registration Eurotransplant Invoice of a lung transplant, heart transplant, kidney transplant, liver transplant, intestine transplant, multi-organ transplant or bone marrow transplant
<b>Immune-compromised people (not HIV)</b>	31-03-2020 to 31-03-2021	From 12 years of age	Invoice of purchase of medication with any ATC code starting with L04 (from 1 DDD)

In total, the insurance institutions activated the data of 332,275 people on 10 September 2021. They received an invitation for an extra dose due to immune problems. This was done on the basis of these parameters and following the same procedure as for the priority patients to be vaccinated.

GPs carried out the decentralised selection for the following groups of patients from 12 years of age:

- Patients with congenital immune disorders who were not being treated with immuno-stimulants;
- HIV patients with CD4 cell counts below 200 per mm<sup>3</sup> of blood;
- Patients with blood cancer or other malignant tumours who had started their active treatment with chemotherapy as of 1 April 2021.

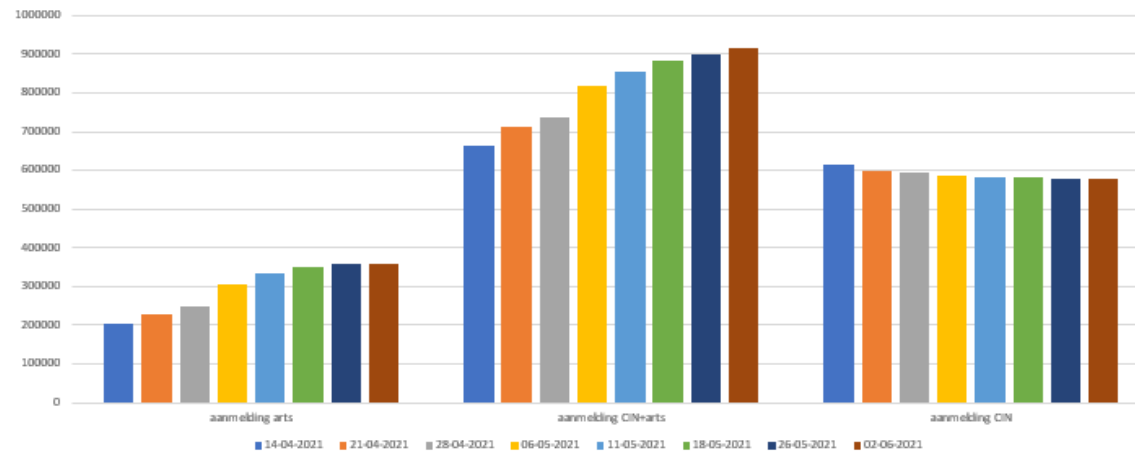
In contrast to the large selection of priority persons to be vaccinated, the decentralised selection for the cohort "extra dose" was limited due to immune problems. It was possible to select the majority based on the IMA data. Therefore, no major adjustments to GP software packages were required. GPs could usually add these patients manually to the selection as of 10 September 2021 at the request of the patient or after referral from a specialist who had recently made a diagnosis, for example.

### 3.4. RESULTS OF THE SELECTIONS

The central selection that took place once on 2 April 2021 was a selection with a broad application of the parameters determined by the Superior Health Council. This *one shot* central selection was followed from 13 April 2021 by the decentralised selections by individual GPs at their own place until 2 June 2021. Of course, general practitioners largely identified the same people as being at risk as the insurance institutions (= CIN + doctor). Some of the selected persons were not confirmed by the GP selection (=CIN) and some of the selected persons were only added by GPs (doctor). The combination of central and decentralised selection meant that people who did not have a GP were selected by the central selection (CIN) and people whose medical data could not be retrieved from the IMA database (see shortcomings) were still selected by their GP. Over the course of the campaign, there was a clear trend: a progressive increase in the number of people who were selected either by a GP or by a GP and the CIN. Nevertheless, more than 500,000 people were only selected by CIN and some 350,000 only by the general practitioner. **Both systems were therefore necessary** to achieve the objective of *equity (leave no one behind)*. A total of 1,852,990 people were selected as being at high risk and required to be vaccinated as a priority. The increase in the week of 6 May can be explained by uploads of priority 3. This was done by GPs only as priority 3 was not identified via the central selection.



**Figure 4: Dynamic overview of the number of patients selected by CIN (health insurance fund-IMA), by general practitioners, and by both**



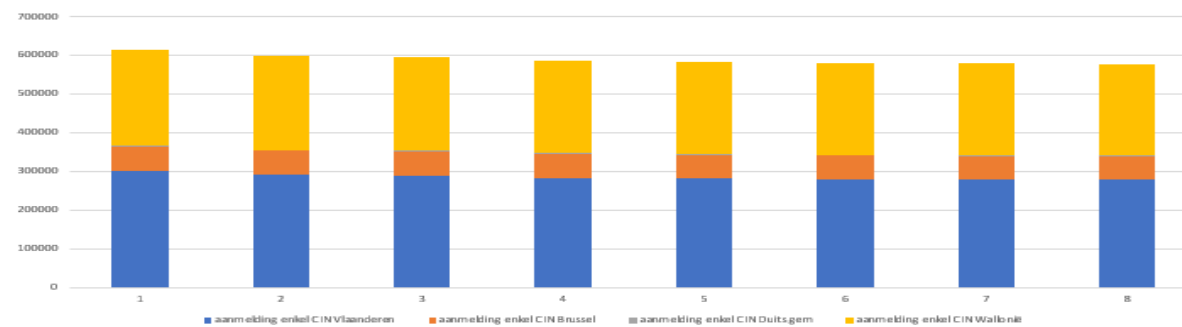
Registration by doctor

Registration by CNN and doctor

Registration by CNN

However, we note significant **regional differences**. Figures 5, 6 and 7 show these regional differences.

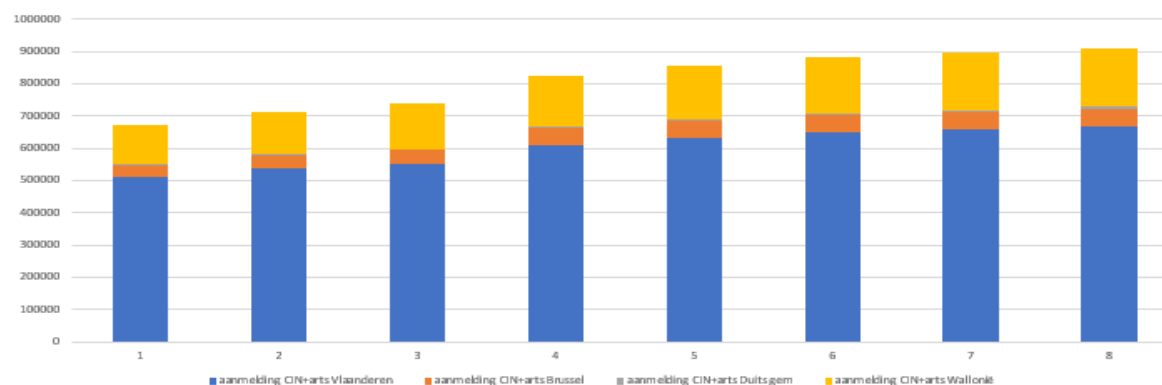
**Figure 5**



Registry by CIN Flanders only  
 Registry by CIN Brussels only  
 Registry by CIN German-speakers only  
 Registry by CIN Wallonia only

Figure 6 shows (for measurements on the same dates as Figure 4) how many persons were selected only by CIN in Flanders (blue), Brussels (orange) and Wallonia (yellow). This remains constant for the regions of Brussels and Wallonia but decreases slightly for Flanders over time.

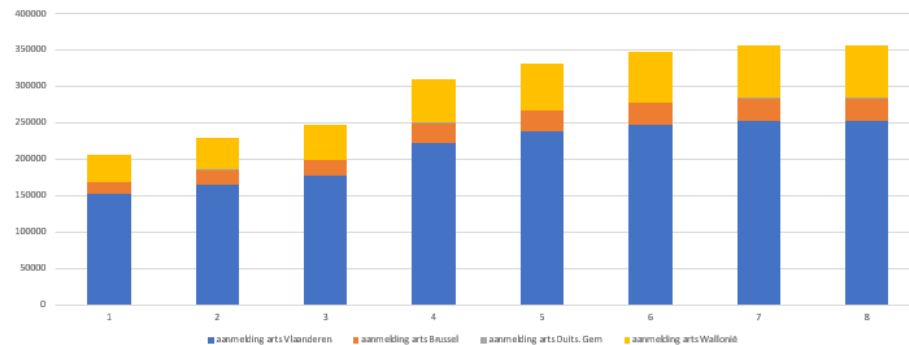
**Figure 6**



Registration CIN + doctor Flanders  
 Registration CIN + doctor Brussels  
 Registration CIN + doctor German Com.  
 Registration CIN + doctor Wallonia

Figure 7 shows (for measurements on the same dates as Figure 4) how many people were selected by CIN and GPs in Flanders (blue), Brussels (orange) and Wallonia (yellow). Here it is clear that as the selection by GPs progressed in Flanders, an increasing number of people were activated by both the central and the decentralised selection.

Figure 7



Registration doctor Flanders  
 Registration doctor Brussels  
 Registration doctor German Com.  
 Registration doctor Wallonia

Figure 7 shows (for measurements on the same data as Figure 4) how many people were selected by GPs only in Flanders (blue), Brussels (orange) and Wallonia (yellow). In all regions, the number of selected persons increased over time, but the increase in Flanders was significantly higher.

The explanation for these regional differences may lie in their different use of the Global Medical Record. The use of the GMD is clearly different (see also Table 1, figures for GMD-holding doctors dated 2019) in each region. The number of doctors managing GMD files is proportional to the population density per region but the number of files per GMD doctor is significantly higher in Flanders. With regard to GMD doctors who use its software package, more patients will logically be selected per GMD doctor as these doctors manage more GMD files on average.

In order to further analyse these regional differences, we make a number of assumptions: we assume that only GMD doctors participate in the selection procedure, that the working method of a GMD doctor is independent of the number of GMD cases he manages, that the incidence and prevalence of co-morbidities is the same throughout Belgium and we give a relative weight to the size of GP practices (1 for < 100 cases, 2 for 100 – 499 cases, 4 for at least 500 cases). A GMD doctor in Flanders selects an average of 130 patients, while in Brussels the figure is 82 and in Wallonia 63, based on data as at 18 May 2021. If we take into account the relative size of the practices, a GMD doctor in Flanders selects 42 patients as high-risk for every 100 GMD files, whereas in Brussels the figure is 35 patients and in Wallonia 23 patients. As the same software packages are used all over Belgium, there is clearly less selection in Brussels and particularly in Wallonia. Not only because there are fewer GMD patients, but also because GMD doctors may have made no or very little use of the software tools offered.

**Table 6: number of cases reported by GMD GPs as having co-morbidities**

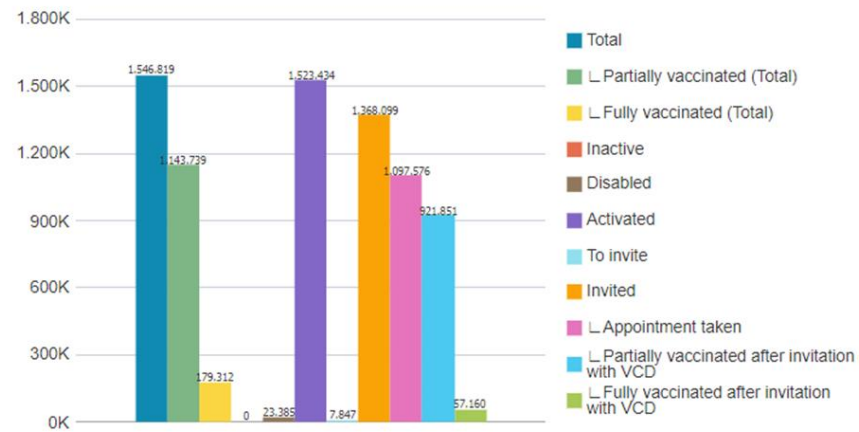
	Number of inhabitants	% GMD patients	Number of GMD holders	< 100 GMD	100-499 GMD	≥ 500 GMD	Selection 18 May 2021	Average	Weighted per 100 files
<b>Flanders</b>	58%	82%	6899 (59%)	1064	1597	4238	894984	130	42
<b>Wallonia</b>	31%	69%	3849 (33%)	881	1183	1785	241560	63	23
<b>Brussels</b>	11%	59%	1039 (8%)	334	365	340	84689	82	35

This may explain the different course of the COVID pandemic in Belgium. In Wallonia, there has been a higher infection rate since the summer and there was a higher hospitalisation rate in the autumn of 2021. Not only is there a lower vaccination rate in Wallonia, high-risk patients have also vaccinated more slowly and at lower rates (relatively less selected and if vaccinated then only invited on the basis of age).

## 3.5 MONITORING TOOLS TO TRACK VACCINATION COVERAGE IN THE HIGH-RISK GROUP ON A DAILY BASIS

### 3.5.1 DASHBOARD VACCINATION ACTIVATION

A dashboard was developed that allows all players involved in the vaccination process to follow the evolution in *real time*. This dashboard provides an overview of the number of people selected, the number of people invited, the number of people partially and fully vaccinated, the number of people who refused a vaccine and the number of people still to be invited. All of these figures are also available per region, even down to the level of a vaccination centre. Separate counters with the same parameters are visible for pregnant women and persons selected for a third dose. This made it possible to adjust based on real figures. Correct information about the progress of the vaccination campaign could be communicated to all with an interest. Figure 8 provides an illustration.

**Figure 8: dashboard Belgium-wide on 28 May 2021 at noon.**

### 3.5.2 COVID-19 VACCINATION BAROMETER FOR GENERAL PRACTITIONERS

#### 3.5.2.1 LOCATION

Doctors are mainly trained to provide *reactive* care: they wait until a patient presents himself for a consultation. But doctors are also responsible for the practice population, in general practice best defined by the GMD population. This population also includes patients who are more difficult to reach, who are less likely to come to the practice, and who do not always receive the care they need in a timely manner. That is why we also need *proactive* care, to identify those vulnerable patients for whom care is more difficult and to identify them in time before serious problems arise. This is also an essential requirement for a successful vaccination campaign.

#### 3.5.2.2 THE DEVELOPMENT OF THE COVID-19 VACCINATION BAROMETER

As a third step for the COVID-19 developments within the EMD systems, a tool was developed to monitor vaccination coverage in general practice. Together with the diagnostic tool and the selection queries for co-morbidities, this third tool forms the basis of the COVID-19 vaccination barometer.

The COVID-19 vaccination barometer can be seen as the third COVID-19 barometer in Belgian general practice. The first barometer was developed to measure the burden, need for assistance, epidemiology and need for protective equipment during the first wave of the pandemic. The second barometer monitored the epidemiology in general practice by surveying the daily incidence of acute respiratory infections, influenza syndrome and COVID-19-related diagnoses.

The Vaccination Barometer is a tool for use in GP practices for proactive care through population management. This tool consists of three steps that enable GPs to complete a quality circle in their practice. The first step is to identify those individuals at risk from among the practice population (see 3.4). The second step is to monitor vaccination coverage in the whole practice population and in specific high-risk groups. As a third step, individual actions are taken to optimise vaccination coverage.

Two databases are very important to make the barometer possible: the VCDB and Vaccinnet. It is possible to obtain figures relating to vaccination coverage because vaccination status is automatically consulted and updated daily for all GMD patients in each GP practice via the VCDB. The VCDB is fed by Vaccinnet as the authentic source for vaccination status information. The vaccination status that appears in the EMD in this way has five values: 1) Unknown status, 2) vaccine refusal, 3) waiting for first vaccine, 4) waiting for second vaccine, 5) fully vaccinated. In addition, general practitioners can consult the detailed information (type of vaccine, date of vaccination and lot number) in each patient's individual file through direct synchronisation with Vaccinnet. But this synchronisation only happens when the patient's file is opened, the GMD is present in the practice and a therapeutic relationship exists with the consulting doctor. The automatic consultation of the VCDB for all GMD patients is therefore essential to make this process efficient, as it would be impossible to open each file individually every day to update the vaccination status.

The third tool consisted of queries to monitor vaccination coverage among the practice population within the different high-risk groups. Five age groups were defined as high-risk groups: +65, 45-64 with and without risk factors and 18-44 with and without risk factors. On the other hand, nine high-risk groups based on socio-economic determinants or morbidity were developed: patients with increased healthcare reimbursement, diabetes, chronic kidney disease, chronic lung disease, chronic liver disease, chronic cardiovascular disease, obesity, chronic neurological disease and oncological disease. In these 14 high-risk groups, three figures were calculated: the total number of active GMD patients within the group, the number of patients waiting for a second vaccine and the number of patients who were fully vaccinated.

Queries were also developed for the five age groups to identify those who had not yet been fully vaccinated. Within these *recall queries*, a further distinction can be made between patients who have refused vaccination, who have an unknown vaccination status, who are waiting for a first vaccine or patients who are still waiting for a second vaccine. These queries are essential to enable the final step of population management (taking individual actions).

GP practices were asked to send in their *performance* on a weekly basis (between Friday noon and Monday noon). With four clicks in the EMD, a GP can calculate the vaccination coverage in his practice in less than one minute and send it to Sciensano (Healthdata) using a structured electronic form (eFORM) in his EMD. HealthConnect developed the eFORM technology, which was installed in every EMD system at the beginning of the COVID-19 pandemic. Among other things, the request for COVID-19 tests is made via eFORMs. For the COVID-19 vaccination barometer, the eFORM is automatically filled in with the figures calculated in the AUDIT. Thus, the GP has no manual work to fill in the eFORM. This avoids mistakes during input. However, administrative data (name of the practice, address, general practitioner, e-mail address, doctors in the practice, EMD system) had to be filled in at the outset. These data were then automatically entered into the eFORM.

The transmitted data were used to provide GP practices with individual feedback on their own performance (prevalence of chronic diseases and vaccination coverage), using practices in their network as a benchmark. Each participating practice can view its own data securely on the Healthstat platform. Because a practice can thus position itself in relation to the other practices in the chosen network, it can be encouraged to improve its performance when, for example, it falls below the average. As a benchmark, one can choose either a geographical area (primary care zone (Flanders only), district, province, region, country) or the type of practice you have (either no selection, so then comparison with all types of practices, or comparison with one's own type of practice (solo practice, duo practice, group practice, district health centre or network practice)).

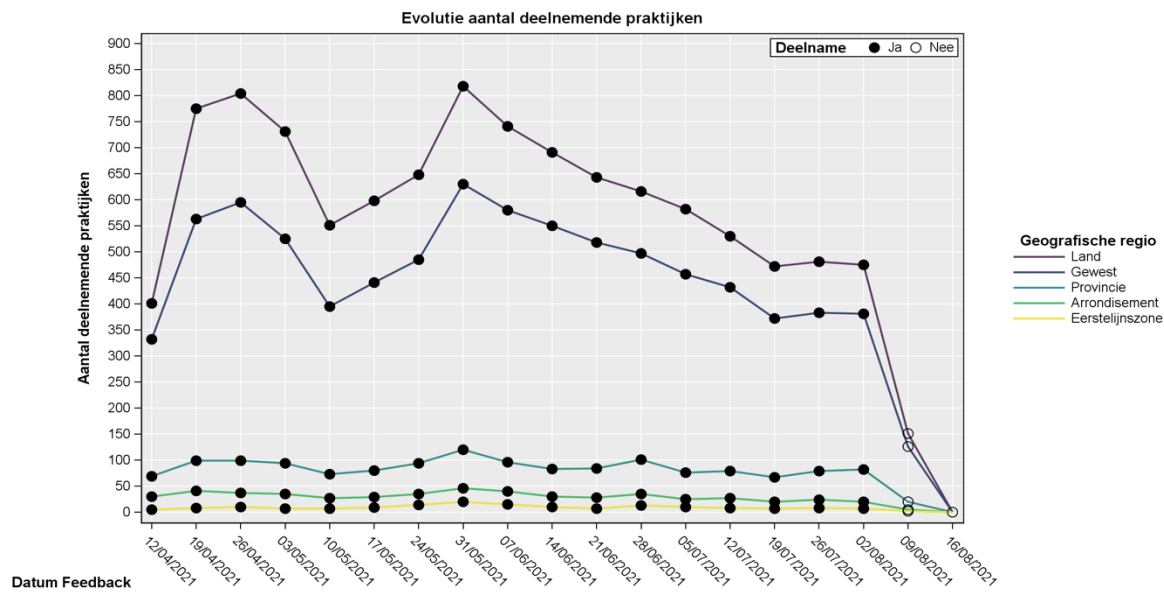
In Flanders, the aggregated data were also used by the primary care zone population managers (ELZ) linked to the vaccination centres. Via a replica database, the barometer data were also made available to the Agency for Care and Health via Healthdata. Flanders has 60 ELZs that are responsible for organising vaccinations in their area. The population managers monitor the vaccination coverage in their area with the help of a dashboard provided by the Agency for Care and Health. They attempt to optimise vaccination coverage in their area through targeted actions. The barometer data are only made available in aggregate. Thus, the population managers cannot view practices' individual performance data, but rather only data at the ELZ level. However, the population managers can identify individual practices on their ELZ map.

The final step of population management involved taking individual actions. If a practice noticed that vaccination coverage remained lower in a particular age group, recall queries could be used to identify the unvaccinated. From this query, further action could be taken, such as putting a task in these patients' file, contacting them by phone or writing a custom letter from the GP. In Flanders, a collaboration between GP practices and the population manager was also possible in order to examine together which actions appeared to be most necessary, for example a larger action within a certain target group in the ELZ or an action targeted at individual patients in the GP practice.

### 3.5.2.3 THE RESULTS

By 13 August 2021, 1,733 practices in Belgium had already sent in the vaccination barometer at least once. Between 450 and 800 practices sent in their data every week. During the holiday period, practices' weekly participation decreased.

Figure 9



Evolution number of participating practices

Number of participating practices

Date feedback

Geographical region

Country

Region

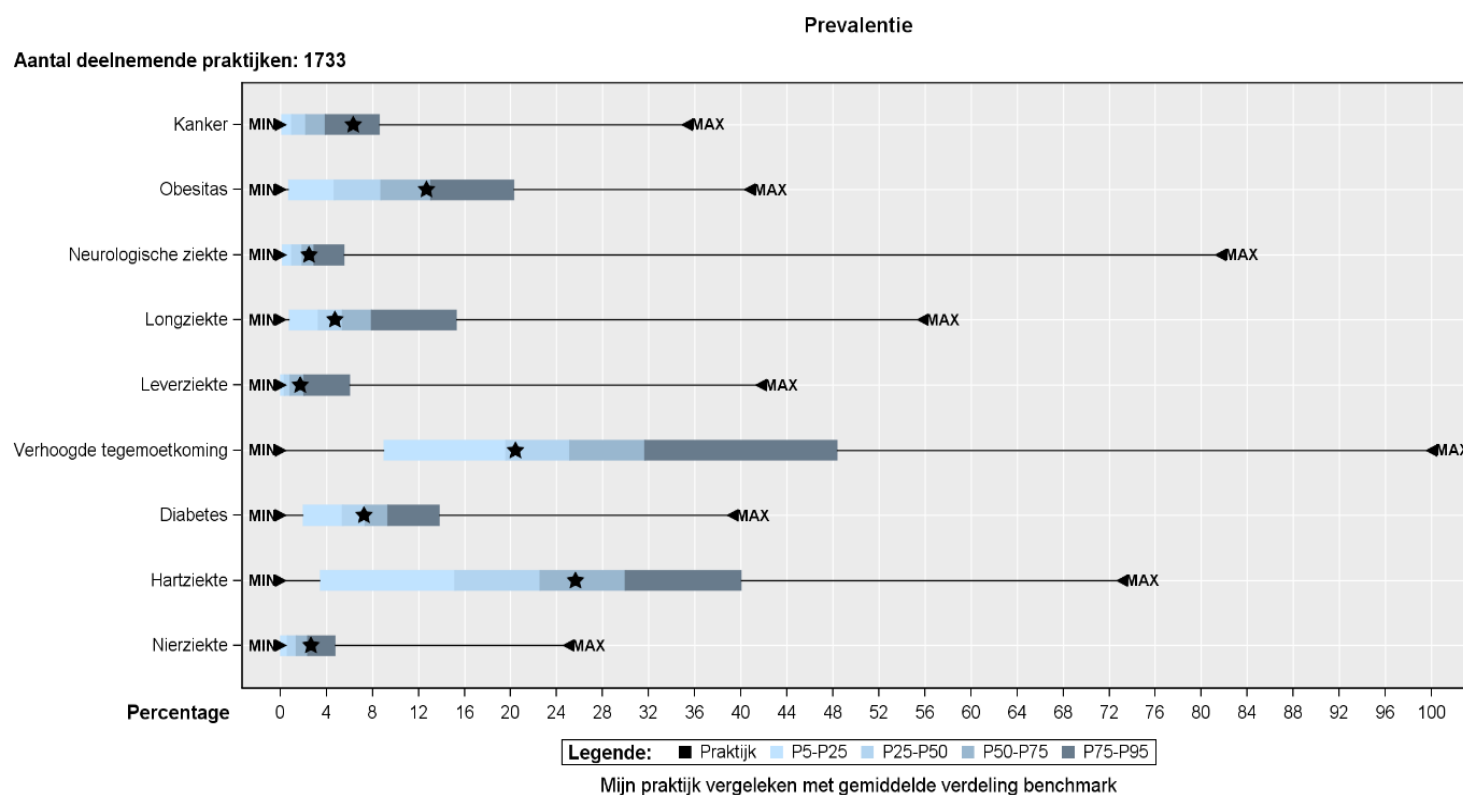
Province

District

primary care zone (ELZ)



Figure 10



Prevalence

Number of participating practices: 1733

Cancer

Obesity

Neurological disease

Lung disease

Liver disease

Increased benefits

Diabetes

Heart disease

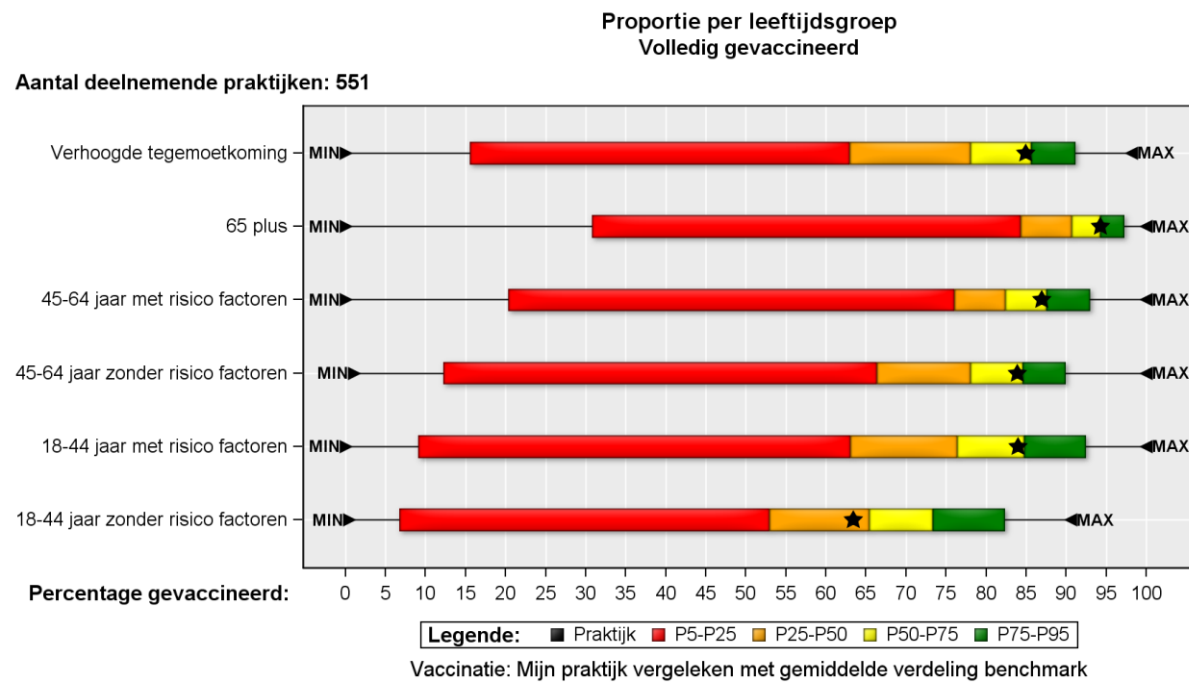
Kidney disease

Percentage

Legend: Practice P5-P25 P25-P50 P50-P75 P75-P95

My practice compared with average distribution benchmark

**Figure 11**



Proportion per age group

Fully vaccinated

Number of participating practices: 551

Increased benefits

65 Plus

45-64 years with risk factors

46-64 years without risk factors

18-44 years with risk factors

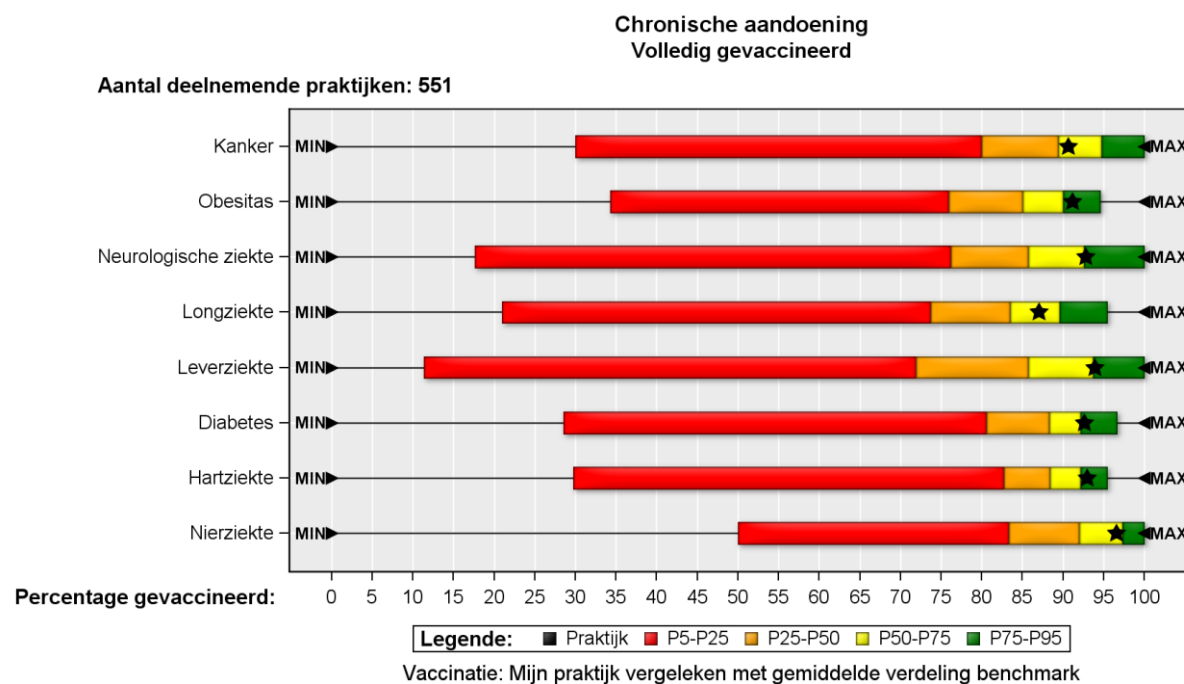
18-44 years without risk factors

Percentage vaccinated:

Legend: Practice P5-P25 P25-P50 P50-P75 P75-P95

Vaccination: My practice compared with average distribution benchmark

Figure 12



Chronic disease

Fully vaccinated

Number of participating practices: 551

Cancer

Obesity

Neurological disease

Lung disease

Liver disease

Diabetes

Heart disease

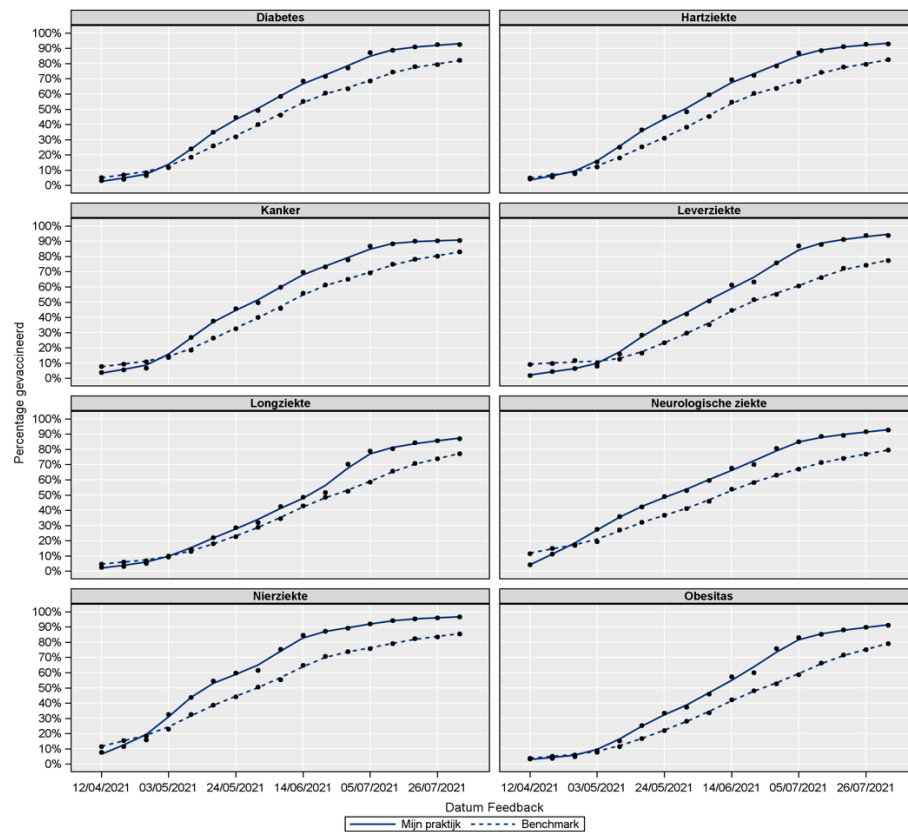
Kidney disease

Percentage vaccinated

Legend: Practice P5-P25 P25-P50 P50-P75 P75-P95

Vaccination: My practice compared with average distribution benchmark

Figure 13



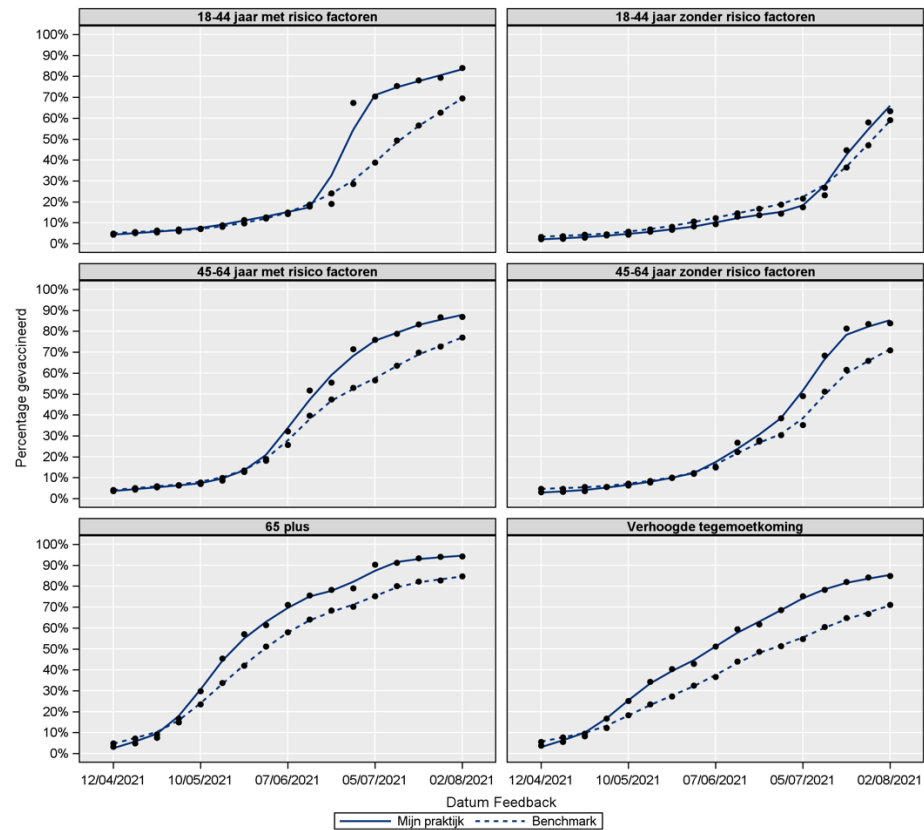
Diabetes Heart disease

Cancer Liver disease

Lung disease Neurological disease

Kidney disease Obesity

Figure 14

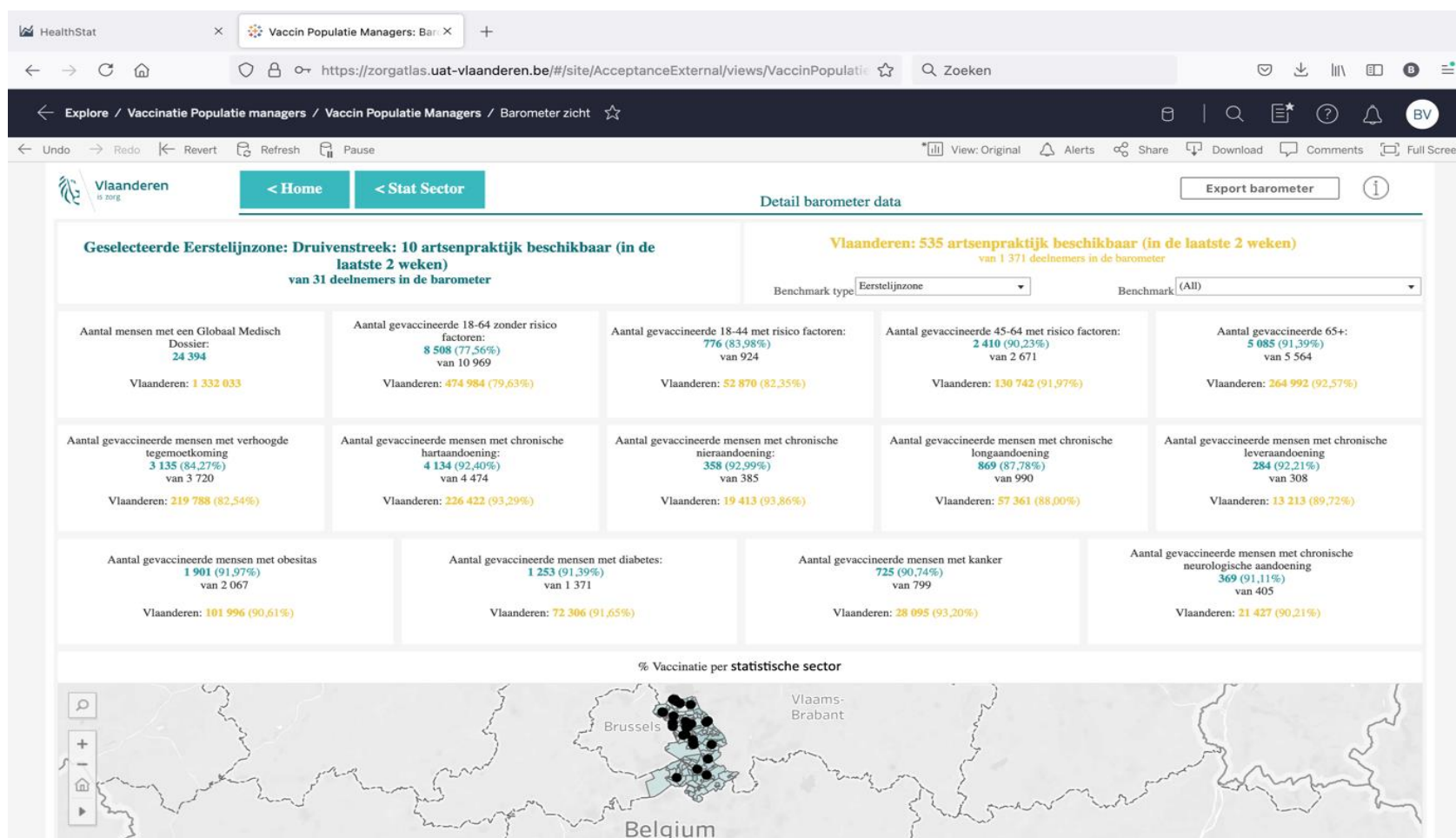


18-44 years with risk factors 18-44 years without risk factors

45-64 years with risk factors 45-64 years without risk factors

65 Plus increased benefits

Figure 15



Selected primary care zone: Druivenstreek region: 10 GP practices available (in the last 2 weeks) from 31 participants in the barometer

Flanders: 535 GP practices available (in the last 2 weeks) from 1371 participants in the barometer



Number of people with a Global Medical Record: 24,394 Flanders: 1,332,033	Number of vaccinated 16-64 without risk factors: 8,508 (77.56%) of 10,969 Flanders 474,984 (79.63%)	Number of vaccinated 16-64 with risk factors: 776 (83.98%) of 924 Flanders 52,870 (82.35%)	Number of vaccinated 46-64 with risk factors: 2,410 (90.23%) of 2,671 Flanders 130,742 (91.97%)	Number of vaccinated +65: 5,085 (91.39%) of 5,564 Flanders 264,992 (92.57%)
Number of vaccinated people with increased benefits: 3,135 (84.27%) of 3,720 Flanders 219,788 (82.54%)	Number of vaccinated people with chronic heart disease: 4,134 (92.40%) Flanders: 226,422 (93.29%)	Number of vaccinated people with chronic kidney disease: 358 (92.99%) of 385 Flanders: 19,413 (93.86%)	Number of vaccinated people with chronic lung disease: 869 (87.78%) of 990 Flanders: 57,631 (88.00%)	Number of vaccinated people with chronic liver disease: 284 (91.92%) of 308 Flanders: 13,213 (89.72%)
Number of obese people vaccinated 1901 (91.97%) of 2067 Flanders: 101,996 (90.61%)	Number of vaccinated people with diabetes 1,253 (91.39%) of 1,371 Flanders: 72,306 (91.65%)	Number of vaccinated people with cancer: 725 (90.74%) of 799 Flanders: 28,095 (93.20%)	Number of vaccinated people with chronic neurological disorder: 369 (91.11%) of 405 Flanders: 21,427 (90.21%)	

Barometer technology also opens up many possibilities for the future. It will be possible to provide GP practices with tools to evaluate the quality of their care, formulate goals for quality improvement within their practice and monitor the impact of their actions. The next step will be to offer Healthstat feedback directly in the GP's EMD. A diabetes barometer is set to be developed in 2022. This will help general practitioners to evaluate and adjust the quality of their diabetes care. As demonstrated by the vaccination barometer, these data also help us to monitor health within the ELZ in Flanders and to track the impact of actions taken within the ELZ. With the barometer principle, we therefore underline the social role of general practitioners and their EMD.

## 4 COST OF PRIORITY VACCINATION

It is impossible to calculate precisely the additional cost of priority vaccination compared to vaccination according to age. In fact, it is extremely difficult to make a proper assessment at all. Nonetheless, we have attempted to do so because, in part 2 of this report, we seek to compare this cost with the policy's outcome.

During the vaccination process, the main focus was on the concrete implementation. This was made possible by great solidarity and enthusiasm without any time registration. Post factum, we attempt to make a rough estimate of the overall cost of this process. The central selection offers some leads. Here we were able to measure a fraction of the activities in 907 man-days, but most of the activities also in the central selection are no longer measurable. For decentralised selection, it is impossible to identify the time invested by each individual GP. Only the partial reimbursement of the EMD packages by the RIZIV is measurable. Nor is it now possible to measure time invested by VC staff, the staff of the various governments, the staff of SMALS, Doclr and Qvax who had to make additional efforts to make this priority vaccination possible. For approximately 3.2 million injections that were prioritised, we reach an overall additional cost of between €1.3 million and €2.6 million.

All things considered and with the necessary caution, we arrive at an additional cost of between €0.40 and €0.60 per dose for priority vaccination.

## 5 AWARENESS-RAISING ROLE OF THE PHARMACIST

### 5.1 STARTING POINTS

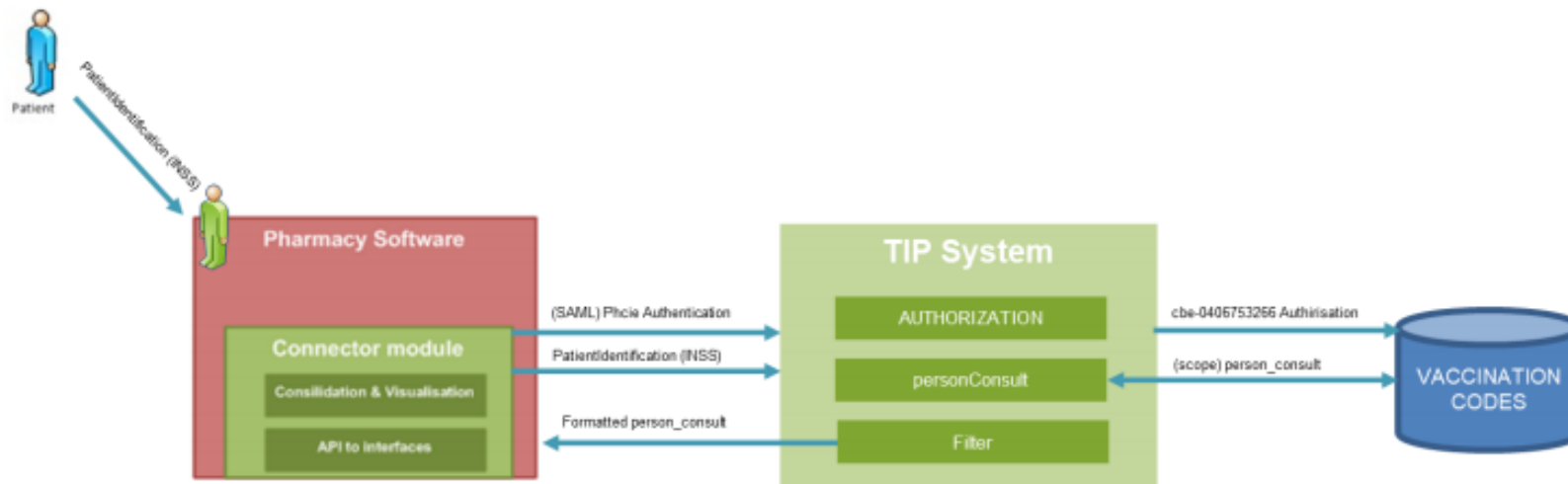
Pharmacists played a role in awareness raising and referral to vaccination. To support their patients, official pharmacists were given access to certain data in the Vaccination Codes database. The information could be accessed when the person's pharmaceutical file was opened. This way, pharmacists quickly and efficiently had information on where the person was exactly in the vaccination process (person invited, vaccinated with first dose, or fully vaccinated).

The development of the pop-up was started in early 2021. This was done in cooperation with FarmaFlux and all the software companies for the publicly opened retail pharmacies. This provided all Belgian general pharmacists with support in their awareness-raising role.

### 5.2 TECHNOLOGICAL IMPLEMENTATION

The priority was to develop a technological solution that would support all pharmacists in a uniform, safe and efficient manner. After identifying the patient, the pharmaceutical record opened. The pharmacy software then sent a call to a central TIP (Trusted Intermediate for Pharmacist) system. This existing system guaranteed high-quality data processing for pharmacists. The TIP system consulted the Vaccination Codes database. An interpretation of the data was then carried out, and the information for the pop-up was prepared. Finally, the software displayed the information in the pop-up to make it visible to the pharmacist.

**Figure 16: dataflow – data from the Vaccination Codes database displayed for pharmacists.**



The pharmacist's access to the Vaccination Codes database was restricted to persons with whom the pharmacist had a therapeutic relationship. The pharmacist was given the right to read the minimum data required to support the further processes of vaccination:

- the assigned vaccination code;
- the activation date of the vaccination code;
- the type of vaccine that would be administered based on the vaccination code;
- the date of first vaccination;
- the name of the second vaccine, if required;
- the vaccination status of the person (possible values: not yet vaccinated, first vaccine administered but second vaccine still required, fully vaccinated).

The data was not stored in the pharmacist's software.

### 5.3 DESCRIPTION OF THE INTERVENTION

In the pop-up, the information from the Vaccination Codes database was visually displayed as a pathway.

The pharmacist was given the opportunity to handle the pop-up. Pharmacists could indicate in each pop-up whether the person was convinced, doubtful, reluctant or needed to be referred. There was also an option *later* for the interview to be postponed. The pharmacist could use the *convinced* option to ensure that the pop-up did not reappear. For those not convinced, the pharmacist evaluated the need for further follow-up. Using the *doubtful or reluctant* options, the pharmacist could leave the pop-up active so that the conversation could take place again at a later time. If a person refused several times, the pharmacist could indicate this so that the pop-up was no longer shown.

### 5.4 RESULTS

Data collection started on 1 May 2021. This report contains data up to 16 August 2021. The total number of active pharmacies in Belgium on 16 August 2021 was 4,695, of which 2,564 were in Flanders, 529 in Brussels and 1,602 in Wallonia.

A total of 4,456 activated pharmacies used the data from the Vaccination Codes database.

Pharmacists opened 4.28 million pop-ups. A total of 891,940 responses were registered in the pop-up, by a total of 3,347 participating pharmacies.

**Figure 17: Results on how the pop-up was handled by pharmacists. In total, this pop-up was answered 259,736 times (date 16-08-2021).**



Brussels Capital Region

N= 11511

Flanders

n= 207 546

Wallonia

n= 40 679

The participating pharmacists received an individual pharmacy report. With a benchmark they could compare themselves with the average figures in their region (Brussels, Wallonia or Flanders) and with national figures. The pharmacy report was used to motivate pharmacists during the vaccination campaign.

## 5.5 FUTURE – LESSONS LEARNED FOR NEXT PHASE

Pharmacists have made a major professional contribution to the vaccination campaign. In doing this, they were supported by innovative technological developments. The pop-up enabled pharmacists to be part of the awareness raising discussion based on their relationship of trust with patients. The central Vaccination Codes database was crucial in providing accurate, real-time information on patient status (invited, partially vaccinated or fully vaccinated). Through a central TIP system, the information could be made available to all Belgian pharmacists in a uniform and secure way.

However, pharmacists played no role in the selection of high-risk patients. In a next sustainable phase, pharmacists could reinforce decentralised selection by general practitioners in two ways. On the one hand, by detecting patients who do not yet have a Global Medical Record and referring them to their GP. On the other hand, the pharmacist could detect and select patients based on a medication algorithm in the pharmaceutical record. The shared pharmaceutical record (GFD) provides all pharmacists in Belgium with relevant, accurate and high-quality information about the medication dispensed to patients. 99% of all Belgian pharmacies are connected to it. Based on this selection, pharmacists could join forces with general practitioners (and possibly other healthcare providers) to further bolster decentralised selection within the interpersonal therapeutic relationship between healthcare provider and patient.

## 6. PATIENT ORGANISATIONS: ROLE AND IMPACT IN THE PROCESS

### 6.1 PATIENT ORGANISATIONS IN BELGIUM

Both umbrella organisations of patients' associations were represented in the working group. In Dutch-speaking Belgium, this was done by the Vlaams Patiëntenplatform (VPP). In French-speaking Belgium, La Ligue des Usagers des Services de Santé (LUSS) took the lead.

### 6.2 IMPORTANCE OF PATIENT PARTICIPATION IN THE PROCESS

At the beginning of the vaccination campaign, the supply of vaccines was insufficient to vaccinate the entire population immediately. The government therefore had to decide which groups in the population would be given priority. The VPP and LUSS took the view that the available vaccines should be administered to high-risk patients as a priority. These patients were at the highest risk of becoming seriously ill and, in the worst case, dying, due to their underlying condition(s). The Superior Health Council's opinion also supported this approach. The VPP and LUSS have always worked to ensure that the Superior Health Council's opinion on this issue is followed. During the Working Group meetings, patient representatives also stressed the importance of priority vaccination for patients at risk.

### 6.3 ROLES TAKEN BY THE PATIENTS' ASSOCIATIONS

The VPP fulfilled the role of advocate for persons with chronic illness or disease, see below. Patient organisation leaders were able to ensure that the experience of chronically ill people was taken into account during Working Group meetings, so that communication to the general public could be as realistic as possible.

The VPP received many questions from patients and patient associations about vaccination and tried to answer them as best it could.

The VPP and LUSS also fulfilled a signalling function in this respect. They acted as an intermediary for questions and concerns from patients and patient associations that the VPP and LUSS could not immediately answer. The working group then drew up an answer. The contacts with individual members also helped.

The patient representatives themselves actively disseminated information about the vaccination campaign through various channels:

THE VPP:

- On 23 February 2021, the VPP organised a webinar on vaccination with great interest, in which prof. Dirk Ramaekers explained the different vaccines, the vaccination strategy and also answered patients' questions. This webinar was a great success. About 200 individual patients participated.
- In the period February – December 2021, the VPP sent an additional monthly Newsflash to all member associations. It was entirely dedicated to the vaccination campaign. In turn, patient associations played an important role in disseminating this information to their own members.
- At the beginning of April, the VPP organised a meeting for the member associations. At that meeting, the patient representatives were given all the necessary information about the selection of high-risk patients, how to find out whether they had been selected or not, and so on. The operation of MyHealthViewer was also explained in detail.

- Ilse Weeghmans, the then director of the VPP, explained on Radio 1 how patients could check whether they were on the list of high-risk patients.

LUSS:

On 24 February 2021, LUSS organised a webinar on COVID-19 vaccination in collaboration with Professor De Wit from CHU Saint-Pierre in Brussels. Members of patient associations could ask questions about vaccination and vaccination strategy.

In March 2021, LUSS organised several discussion forums in small groups.

In the period from December 2020 to June 2021, communication about the vaccination campaign was sent through various channels. There was also awareness-raising to encourage patients to request a Global Medical Record (GMD) in order to optimise the selection of high-risk groups.

The VPP and LUSS also helped to adapt the information disseminated by the government to the needs of patients.

## 6.4 IMPACT OF PATIENT ORGANISATIONS

Initially (December 2020), only patients with underlying conditions of 45 years and older were considered at risk. The Vlaams Patiëntenplatform and the Ligue des Usagers des Services de Santé worked to expand this target group to include high-risk patients under the age of 45. The organisation has raised this issue several times with different policy authorities. The Vlaams Patiëntenplatform invested significant time in meetings and contacts with policy makers to make sure that the vaccination strategy would be adjusted. At the beginning of December 2020, the organisation sent out a press release to back up its demand. At the beginning of February 2021, the Superior Health Council added a number of patient groups to the list of high-risk patients in a new advisory report.

As time went on, it became apparent that not all the partners involved were keen on the agreed vaccination strategy. Eventually, some politicians also spoke out. There was a desire to stop prioritising high-risk patients and instead vaccinate according to age. In the Working Group itself, support for the agreed vaccination strategy remained very high. The VPP sent out a number of press releases, in which it emphatically asked for the agreed vaccination strategy to be maintained. It also contacted the federal, Flemish and Brussels governments for this purpose and informed the MPs of the parliamentary committees involved. At the beginning of March 2021, the VPP called on its members to issue their own press release, advocating the retention of the agreed strategy. The VPP also asked its members to share videos on social media with the title 'I am a high-risk patient. Will you ensure I'm vaccinated fast?'. La LUSS and RadDiOrg supported and shared the campaign with their networks.

When designing the vaccination strategy the specific needs of patients with rare diseases were also taken into account. These people risked being left out because their situation was often unknown to both their general practitioner or their health insurance company. Therefore, reference doctors in hospitals were given responsibility for the selection of these patients. The VPP and LUSS ensured that the needs of this patient group continued to be addressed in the Working Group.

At the inter-ministerial conference on 10 March, the agreed vaccination strategy was finally endorsed. The commitment of the other members of the Working Group, especially the health insurance companies and the general practitioners, was of the utmost importance for the successful vaccination of the high-risk patients.

In the course of the vaccination campaign, it became clear that young people as young as 12 years old could also be vaccinated. The VPP also asked that young people with underlying conditions be given priority for vaccination.



In May, the interval between two doses of the AstraZeneca vaccine was reduced to eight weeks. This decision only applied to persons invited after 13 May 2021. For people who had been invited earlier, the interval between the two doses remained at twelve weeks. Since this mainly concerned people over 65 and high-risk patients, who had been given priority in the campaign, the VPP helped to ensure that these people, too, would receive their second jab earlier. This allowed them to be optimally protected four weeks ahead of schedule.

In July, a survey by the VPP showed that 8 out of 10 people with chronic illnesses believe that COVID-19 vaccination should be mandatory for all healthcare providers. The VPP felt that such a powerful signal had to be grasped. Compulsory vaccination was necessary, according to the organisation, to protect the most vulnerable patients or residents with whom healthcare providers come into contact. For them, COVID-19 remains life-threatening.

## 7 COMMUNICATION: CONTINUOUS CONSULTATION WITH AND PROVISION OF INFORMATION TO ALL STAKEHOLDERS

The members of the Working Group communicated with patients, healthcare providers and the relevant administrations, among others. Additional communication initiatives were taken by the Vaccination Task Force to raise awareness and inform all stakeholders and the general public:

- press releases + interviews with the press
- announcements at the weekly press conferences of the Task Force and the National Crisis Centre (NCCN)
- mailings to the doctors-specialists and hospitals concerned with information about the procedure to be followed (see <https://www.info-coronavirus.be/nl/vaccinatie/#adviezen>)
- webinars by the Task Force's virologists
- information on the website [www.info-coronavirus.be](http://www.info-coronavirus.be) (including videos and FAQs) with accessible, multilingual communication
- posters for the priority vaccination of pregnant women sent to gynaecologists and midwives:  
[https://d34j62pglfm3rr.cloudfront.net/downloads/2021\\_zwanger\\_LR\\_NL.jpg](https://d34j62pglfm3rr.cloudfront.net/downloads/2021_zwanger_LR_NL.jpg)

## 8 PRIORITY VACCINATION AND EQUITY

The introduction referred to *equity* as an important starting point in the implementation of the vaccination strategy. Firstly, the *Leave no one behind* objective is achieved by focusing on accessibility.

In Flanders, a population manager was appointed for each primary care zone. They were responsible for achieving the highest possible vaccination coverage in all target groups of the population in their primary care zone. To achieve this, the population manager monitored the vaccination coverage per target group, analysed the target groups' needs and developed targeted actions where necessary. This was done in cooperation with all care and welfare partners in primary care. In addition, the population manager was responsible for coordinating home and mobile vaccination in communities and *outreach* to vulnerable groups.

The population managers paid special attention to target groups that are socially vulnerable or might experience certain barriers in responding to their invitation to be vaccinated. Extra attention was paid to target groups that could not easily travel to a vaccination centre and required vaccination at home or in familiar surroundings. The population manager worked with a mobile team of healthcare professionals from the vaccination centre, or a local GP carried out the mobile vaccination. GPs vaccinated many of their non-mobile patients at home, in cooperation with the vaccination centre, where the shots were prepared.

Vaccination events took place in many different settings, such as places of worship, drop-in centres, shelter initiatives, but also very informal settings like cafés. Whenever possible, mobility solutions were also used so that people could still be vaccinated at the vaccination centre, together with like-minded people, which was a confidence-building factor.

Furthermore, special attention was paid to people who had difficulties with their invitation to be vaccinated due to a language or cultural barrier. Targeted actions were also taken for youth vaccination to overcome practical and other barriers. In addition, attention was paid to many specific target groups, which differed from one primary care zone to another. The starting point for the population manager was always to set up the most targeted action possible to address the needs experienced by a particular group of people. Cooperation with all possible partners in the field was extremely important to complete this task. The population manager took on a liaison role to identify all available data on possible challenges to vaccination and act with the network. It was also crucial to have quantitative data available in a dashboard to track vaccination coverage by age and statistical sector within the primary care zone. This was made possible by the Care Atlas of the Flemish Agency for Care and Health.

In Brussels, a study was carried out on behalf of the Joint Community Commission (<https://www.ccc-ggc.brussels/> and the Brussels Capital Region's Health and Well-being Observatory) under the name *Vaccessible*. The strategy in Brussels was based on diversification and decentralisation. There was a switch from a *one-size-fits-all* strategy to the development of a broad offer (central vaccination and accessible local vaccination in local neighbourhoods).

The following steps were taken:

- The needs of the population were identified: needs related to accessibility, population perception of risks, population confidence in vaccines and vaccinators, etc
- Approach: adapted communication, complementary actions (large vaccination centres combined with decentralised actions such as the Vaccibus).

Three main conclusions emerge from the study:

- The starting point to determine the vaccination strategy must be the needs of the population. A methodology with categories has been developed.

- For a sustainable approach, it is important to promote multiple complementary actions to meet the needs of the population.
- For integrated action, the active intervention of health actors should be taken into account.

Throughout the study, the scientific researchers and staff involved in strategy formulation worked closely together. It was a continuous process of research, evaluation and adjustment.

The results of the study are important for a sustainable strategy in the future.

## 9 'LESSONS LEARNED' FOR THE FUTURE ORGANISATION OF HEALTHCARE AND THE IMPORTANCE OF POPULATION MANAGEMENT IN THE CASE OF URGENT IMPLEMENTATION OF LARGE-SCALE HEALTH-RELATED PROJECTS.

In this section, we look at the main lessons learned from the campaign with regard to selecting people for priority vaccination. A general observation is that priority vaccination only really works if it is part of a well-functioning general vaccination campaign.

This chapter was developed through a broad participatory process in the Working Group on Organisation of the Vaccination Strategy Task Force. We have broadened the scope beyond the vaccination of high-risk groups, as the Working Group has undertaken many other tasks in the course of the past few months in the context of implementing the vaccination strategy. The reflections in this chapter are also relevant in the context of a 'well-functioning vaccination'.

### 9.1 WHAT HAVE WE LEARNED AT THE MACRO LEVEL?

To enable the priority selection of persons for vaccination, important factors had to be taken into account in the following areas:

- Belgium's administrative structures
- Legal framework
- Available electronic information sources
- Organisation of the "Frontline
- Information flow

9.1.1 Despite a complex intervention with a complicated **administrative structure**, regardless of who is in charge, it is important that the various levels continue to speak to each other. This was fairly successful with regard to the Vaccination Strategy. What we have clearly learned is that the "Working Group on Vaccination Strategy Organisation" has added value in determining the operational process approach and the implementation of the chosen strategy. A fixed schedule of weekly consultations ensured support for the operational procedures. The decisions concerning the implementation of the strategy were prepared with input from multiple perspectives (healthcare providers, patients, health insurance funds, federated states, communication managers, IT managers, lawyers, etc.). In addition, the important focus on mutual reporting led to a kind of informal learning community where best practices were exchanged and solutions were developed in a co-creative manner. Monitoring the synchronisation of decisions and properly anticipating bottlenecks was intended to ensure that one level did not have to wait or be short-changed by another. Retaining a general overview is a challenge in this context and deserves attention.

Setting up a platform with all actors involved in the implementation certainly created added value.

9.1.2 Initially, there was no **legal framework** specifically for such a campaign meaning we had to fall back on existing 'non-adapted' legislation. As a result, often cumbersome procedures had to be repeated at each new step in priority vaccination. Therefore, a thorough reflection on a sustainable, GDPR-compliant integrated

approach in a high-performance legal framework is a task of the highest priority. It is necessary to develop a framework that brings together the various competent authorities. During the campaign, this led to the Cooperation Agreement of 12 March 2021 between the Federal State, the Flemish Community, the French Community, the German-speaking Community, the Joint Community Commission, the Walloon Region and the French Community Commission on the processing of data relating to vaccinations against COVID-19.

It is also important that during a pandemic, existing databases run by different authorities can be linked up so that the necessary vital information can be used to protect the population. A generic legal framework of data sharing is needed, within which vaccination campaigns for future pandemics can be rapidly rolled out.

**9.1.3 A well-developed information system** that goes beyond the individual authorities involved is an essential prerequisite to manage a crisis. For the selection of high-risk patients, a unique cooperation was realised between the Vaccination Codes database, the IMA, the mutual health insurance companies, general practitioners and their GMD, pharmacists and their IT systems, specialist physicians, E-health services, ...

An "integrated interprofessional electronic patient record" with structured architecture is an important essential link. "Equity" is an important consideration in the development of an electronic patient record and calls for attention to "digital literacy" and "health literacy". The patient record is not an end in itself, it is a means to achieve the "quintuple aim" (see Chapter 1). In other words, the e-patient file for every Belgian citizen must contribute to greater health and well-being, with the healthcare team as an active partner. And this regardless of the extent to which the citizen can take control of their own health.

The strength of this campaign was the complementary effect between the data available in the GMD files and the data of the IMA that could be allocated to national register numbers via the mutual health insurance companies. In this way, there was a maximum possible guarantee that no one would be left out. The mutual health insurance companies have the data on the reimbursed use of care, and thus indirect medical information, of every citizen, regardless of the citizen's level of health literacy. Because of the complementary effect, the responsibility did not fall on one sector and pressure on the front line was to some extent 'relieved' while they were in the line of fire. The integrated file – together with central databases such as the IMA database – forms the basis for population management, whereby anonymised or pseudonymised data are extracted in compliance with GDPR, on the basis of which a 'community diagnosis' is drawn up, which can inform strategies adapted to local needs. This anonymised or pseudonymised data are the data source for population management; dashboards offer the possibility to access data on different levels (micro, neighbourhood, meso, macro). A system for benchmarking and quality improvement can be set up from these dashboards. Tools can be used for awareness-raising, personalised approaches, audits, quality cycles, benchmarking. All this supports follow-up by the healthcare provider, the GP's practice or pharmacy, the own organisation of e.g. home care nurses. Tools are also needed for reporting, monitoring and visualisation at neighbourhood, ELZ or regional level. In this way, the role of the mutual health insurance companies in raising awareness can also be more targeted.

**9.1.4 Within the health system, primary care must be strengthened.**

There is a markedly lower vaccination coverage for both the general population and high-risk patients in the regions where fewer residents had a GMD, where GMD-holding GPs selected patients less actively and where the number of GMD patients per GMD doctor was lower.

Firstly, the capacity of primary healthcare providers must be strengthened and diversified. In the short term, 400 extra FTE general practitioners are needed in Brussels, and in many areas in Wallonia and Flanders there are capacity problems regarding general practitioners, home nursing and other care professions.

On the occasion of the Primary Care Conference in February 2017, the Wetenschappelijke Reflectiekamer [Scientific Reflection Forum] wrote a paper entitled: "De hervorming van de eerstelijnszorg in Vlaanderen: we maken er samen werk van!" [The reform of primary care in Flanders: we make it happen together!] (<https://www.zorg-en-gezondheid.be/sites/default/files/atoms/files/CELC-Synthesenota%20Wetenschappelijke%20Reflectiekamer%202017.pdf>).

Secondly, the concept of 'Primary care network' is an interesting one.

The principle of 'registration in a primary care network' is an extension of the integrated interprofessional electronic record and offers every citizen the added value of receiving interdisciplinary, custom care from nearby care teams that are active in the neighbourhood. The primary care networks ensure a smoother care coordination in the first instance, focusing on health and well-being, and cooperate with hospital networks and with specialist care in the second instance. Further research into these possibilities is needed.

9.1.5 Patient organisations emphasise the importance of effective **information flow to healthcare providers and the public**. The Vlaams Patiëntenplatform (VPP) believes that a better flow of communication is needed to healthcare providers in the field.

Healthcare providers play an important role in the vaccination campaign. They themselves must be convinced of the benefits of vaccination in general and of the principles of priority vaccination, otherwise the patient will not be either. It is important that the patient can turn to the healthcare provider for correct information about vaccination.

Given we have been fighting an unknown virus, the correct scientific information has evolved and there has been a progressive understanding of the strategy to be adopted regarding priority vaccination.

There was indeed a lack of a single central information platform for professionals regarding the priority people to vaccinate. The information was fragmented, often not detailed enough for professionals and often difficult to understand for citizens. A parallel source of information for citizens is also necessary. Although a very commendable contribution was made by the Corona Secretariat information cell, the central coordination of information remained a challenge. In the field, it was not always easy to clearly identify who was disseminating "official information".

It must be clear to the citizen what authority they can turn to with their questions. Experience has shown that this was not (always) the case. Here, too, a good coordination of central and decentralised initiatives (e.g. call centres for information questions) is necessary.

## 9.2 WHAT HAVE WE LEARNED AT THE MESO LEVEL?

A well-developed meso level has clearly contributed to a smooth campaign for the general population and for priority persons to be vaccinated in particular.

In **Flanders**, the Primary Care Zones, in which four clusters work together (healthcare, welfare, people in need of care and support and local authorities), have very quickly highlighted the importance of coordination at the meso level (100,000 inhabitants). The vaccination centres, organised by the primary healthcare zones and involving thousands of volunteers, proved to be the key strategy to put the region in the European top five of the best performing regions for vaccination. Vaccination centres were also used in Wallonia and Brussels – where the meso level is not yet clearly defined – but in Brussels it quickly became clear that a wide range of adapted strategies were necessary to reach the very diverse population (see Chapter 8). On the one hand, the meso level appears to form a sufficient 'critical mass' to efficiently set up large-scale campaigns, and at the same time it offers sufficient connection with the local actors (healthcare professions, care organisations, ...) to flexibly respond to local differences and needs.

It is important that the meso-level is sufficiently supported by the macro-level: in Flanders, the role of the Vlaams Instituut voor de Eerste Lijn [Flemish Institute for the Frontline] ([www.vivel.be](http://www.vivel.be)) and of the Vlaamse Vereniging voor Steden en Gemeenten [Flemish Association for Cities and Municipalities] ([www.vvsg.be](http://www.vvsg.be)) proved to be essential for the Primary Care Zones to function well.

In **Brussels**, at meso-level, vaccination was organised entirely by the Region: planning, invitations, physical organisation and administration, logistics etc. were managed regionally. Primary care was an important partner in this, not an initiator. The leitmotif of the entire vaccination campaign in our cosmopolitan capital region, where 40% of the population does not have a general practitioner, was proximity-accessibility-confidence under the slogan "Leave no one behind".

The implementation of the vaccination strategy was guided by 3 chronological and overlapping approaches:

1. In the first phase, when there was still a shortage of vaccines, the priority groups were followed, as agreed at inter-federal level. Here, the invitation to vaccinate was implemented as mass vaccination in 10 large vaccination centres with efficiency and universality as they key concepts. At the same time, there was specific awareness raising among specific target groups and the invitation process was modified to allow those with limited digital skills to make an appointment at one of the vaccination centres.
2. At the same time, Brussels has focused on an alternative approach, based on the socio-economic needs of citizens. The vaccination offer fitted into the public space and is literally 'on the route passers-by take'. This makes the vaccine accessible and acceptable; taking time, listening, answering questions from local residents in an environment that is familiar to them. This approach fulfils an instant need by working without appointments, offering vaccines to people at the entrance of a shop, a thoroughfare, on the spot in the community for healthcare personnel / schools / businesses, etc. People are always given the opportunity to obtain information and ask questions. This also gives undocumented migrants the opportunity to be vaccinated in a familiar environment. Here, too, there is strong awareness-raising per target group (e.g. young people, certain nationalities, undocumented, etc.).
3. The latter approach is really tailored to those citizens who live somewhat disconnected from mainstream society and media, and for whom healthcare and COVID are not their primary concerns; or who because of their background have a negative attitude towards the vaccine. Here, the first step was to raise the awareness among councillors using the "train-the-trainer" principle, always trying to link medically trained staff to more socially oriented people. After awareness raising, vaccination was provided via vaccination vans or another method. This was used for the vaccination of the homeless, sex workers, vaccination in mosques, ... where the trust goes



beyond the purely medical dimension. In some cases, for very precarious target audiences, breakfast sessions are organised first, where people can get together and talk about all sorts of topics, before moving on to health needs, and from there to the importance of vaccination against COVID.

This involves favouring accessibility or the material conditions of vaccination (e.g. distance, time needed, cost and administrative procedures); acceptability (perception of need and perceived risks of the disease/vaccine); trust in the vaccine, in vaccinators and in the healthcare system.

The strategy in the Brussels Capital Region is one based on proximity, diversification and decentralisation.

From the large vaccination centres (10 in number as of March 2021) to smaller ones, vaccination vans and vaccination points in, for example, schools, places of worship, public social welfare centres, companies, markets, hospitals, at doctors' offices, by home care nurses and in pharmacies. This diversification was only possible through partnerships with municipal authorities, the Red Cross, hospital umbrella organisations, nursing home federations, home healthcare providers and pharmacists' federations, precarious care providers' associations and numerous local companies.

In **Wallonia**, the "meso" level is underpinned by GPs and by outpatient OST (Outbreak Support Teams), implemented by the Minister of Health and the AViQ (Quality of Life Agency) as part of the management of the COVID crisis. They associate GPs, nurses and support services to deal with emergencies outside the hospital.

The COVID-19 General Delegation of the Walloon Region has been charged by the Walloon Government with organising the vaccination campaign in collaboration with the AViQ. In the field, event operators who won the government contract and local general practitioners' associations worked together in fixed vaccination centres in large and medium-sized cities, in mobile vaccination antennae in rural areas and on university campuses. Hospitals have been involved in vaccinating their staff and high-risk patients, while a network of 95 retail pharmacies have facilitated the distribution of vaccines to general practitioners. The vaccination coverage obtained has contributed to Belgium being in the top five of European countries in terms of 2<sup>nd</sup> and 3<sup>rd</sup> dose coverage (situation at the end of January 2022).

### 9.3 WHAT HAVE WE LEARNED AT THE MICRO LEVEL?

We found that there was a great willingness among various groups of healthcare providers to actively engage in vaccinating as many people as possible, complementing the work of the vaccination centres. General practitioners and home care nurses provided vaccination to bedridden patients at home. In Brussels, a network of pharmacists made their pharmacies available to offer low-threshold vaccination immediately after the awareness raising talk. Mobile teams of doctors, pharmacists and nurses provided outreach to hard-to-reach groups: the homeless, residents of asylum centres, facilities for the disabled, caravan dwellers, ... This micro level does have the potential to prioritise vaccination based on the therapeutic relationship.

Through the automatic link between Vaccinnet and the GMD, GPs can monitor the vaccination status of patients in their practice, and motivate people when necessary. Pharmacists can motivate and support people who are not yet 'on the vaccination schedule' to get vaccinated.

### 9.4 CONCLUDING REMARKS: NEED FOR INNOVATION IN DATA, CARE MODELS AND FINANCING MODELS FOR SUSTAINABLE AND FUTURE-ORIENTED HEALTHCARE.

The Working Group on Vaccination Strategy Organisation, originally set up in the context of priority vaccination, is still an active platform where the situation and progress of the vaccination campaign – in all its aspects – are explained, analysed and coordinated on a weekly basis. The participants' involvement and the openness of the discussions reinforce the necessary trust between healthcare actors, policy makers, IT managers, lawyers, communication managers, etc. and make an important contribution to the success of the campaign. A permanent open dialogue with all stakeholders is an important basis, for example, for continuously improving the quality of the data underpinning the various actions.

The following reflections can help shape further discussion with a view to the future:

- **Data is the foundation**
  - The Vaccination Codes database and Vaccinnet are important tools for the selection, planning and follow-up of vaccinations. They should be operationally integrated with the databases for testing, contact tracing, isolation and quarantine.
  - Tools for population management (e.g. follow-up of high-risk groups) and selection by general practitioners and the role of the insurance institutions have been developed and have worked well.
  - It must be possible to use the mega databases held by the insurance institutions and IMA in certain contexts such as a pandemic on the basis of a suitable and flexible legal framework. The division of competence in public health should not prevent the interconnection of existing databases.
- **An innovative integrated funding mechanism encourages population-based care and local cooperation**
  - Encourages multidisciplinary cooperation between local GPs, nurses, general pharmacists and other involved care providers (e.g. social work, community health workers for outreach to vulnerable groups). The goal is neighbourhood-oriented care, with "double accountability". This means that primary networks take responsibility for the citizens enrolled in the network and that the primary care zone is responsible for ensuring that all citizens join a primary network ("to leave no one behind")

- Stimulates the 'intellectual act'. This is population management on the one hand and information and awareness raising within the therapeutic relationship on the other.
- It stimulates efficient use of resources 'right care in the right place', subsidiarity and task-shifting. The aim is to maximise the value of the therapeutic relationship of trust.

- **Promoting strong bottom-up commitment**

- Neighbourhood-based vaccination (and broader 'preventive care') organised by nurses, GPs and general pharmacists. They work together with other care providers (welfare, social work, etc.) for neighbourhood populations. A sustainable model encourages local agreements, e.g. within the framework of a Primary care network.
- Primary care networks – in the context of the Primary Care Zone – make local agreements tailored to the population living in the neighbourhood.
- There is an important role for the primary healthcare centres (or similar structures in Brussels and Wallonia), local authorities, insurance institutions and patient organisations in raising awareness of the importance of prevention. They also play a role in making care services known and accessible, e.g. within a 'caring neighbourhood' concept.
- Attention should be paid to the most vulnerable people and hard-to-reach target groups. E.g. through a flexible vaccination offer (group vaccination, outreach care, home vaccination, opportunity vaccination ...)
- There is an important role for general practitioners' groups, pharmacists' associations, consortia of nurses, in cooperation with social services and local authorities, to organise vaccination locally within the framework of primary healthcare zones.
- The groups are supported by the primary healthcare zones (Flanders) and the local authorities for population-oriented tasks.

Insurance companies, patient umbrella organisations and individual patient associations have a significant role in awareness raising and communication.

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## ALPHABETICAL LIST OF ABBREVIATIONS USED

ATC code	Anatomical Therapeutic Chemical Classification System
AVIQ	Agence pour une Vie de Qualité [Agency for a High-Quality Life]
CLB	Centrum voor Leerlingen Begeleiding [Pupil Guidance Centre]
CM	Christelijke Mutualiteit [Christian Mutual Health Fund]
COCOM	Joint Community Commission
e-FORM	Structured electronic form
EMA	European Medicines Agency
EMD	Electronic medical record
ELZ	Frontline zone
FPS	Federal Public Services
FWB	Fédération Wallonia-Brussels [Wallonia-Brussels Federation]
GMD	Global medical record
GP	General practitioner
SHC	Superior Health Council
IARC	International Agency for Research on Cancer
ICT	Information and Communication Technology

ICU	Intensive Care Unit
IMA	Intermutual Agency
ISC	Information Safety Committee
La LUSS	Ligue des usagers des services de santé [League of Health Service Users]
NIC	National Intermutualist College (pol= political, med= medical, GZ= healthcare)
ONE	Office National de la Naissance et de l'Enfant [National Maternity and Childhood Office]
RIZIV	Rijksdienst voor Ziekte en invaliditeitsverzekering [National Office for Sickness and Disability Insurance]
TF	Vaccination Task Force, Inter-federal Task Force for the operationalisation of the COVID-19 vaccination strategy
VC	Vaccination Centre
VCDB	Vaccination Codes database
VI	Insurance institutions
VPP	Vlaams Patiëntenplatform [Flemish Patients' Platform]
WHO	World Health Organization
WVG	Vlaamse Raad voor Welzijn, Volksgezondheid en Gezin [Flemish Council for Welfare, Public Health and Family]